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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 985

[Doc. No. AMS–SC–16–0107; SC17–985–1A FR]

#### Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2017–2018 Marketing Year

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule implements a recommendation from the Far West Spearmint Oil Administrative Committee (Committee) to revise the quantity of Class 3 (Native) spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which began on June 1, 2017. This rule increases the Native spearmint oil salable quantity and the allotment percentage. This rule also contains formatting changes to subpart references to bring the language into conformance with the Office of Federal Register requirements.

**DATES:** Effective February 6, 2018.

**FOR FURTHER INFORMATION CONTACT:** Barry Broadbent, Marketing Specialist, or Gary D. Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: [Barry.Broadbent@ams.usda.gov](mailto:Barry.Broadbent@ams.usda.gov) or [GaryD.Olson@ams.usda.gov](mailto:GaryD.Olson@ams.usda.gov).

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence

Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: [Richard.Lower@ams.usda.gov](mailto:Richard.Lower@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Order No. 985 (7 CFR part 985), as amended, regulating the handling of spearmint oil produced in the Far West (Washington, Idaho, Oregon, and designated parts of Nevada and Utah). Part 985 (referred to as “the Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Committee locally administers the Marketing Order and is comprised of spearmint oil producers operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the provisions of the Order now in effect, salable quantities and allotment percentages may be established for classes of spearmint oil produced in the Far West. This rule increases the quantity of Native spearmint oil produced in the Far West that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which ends on May 31, 2018.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any

obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule revises the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year under the Order. The salable quantity and allotment percentage for Native spearmint oil was initially established at 1,075,051 pounds and 44 percent, respectively, in a final rule published May 25, 2017 (82 FR 24001). This rule increases the Native spearmint oil salable quantity from 1,075,051 pounds to 1,514,902 pounds and the allotment percentage from 44 percent to 62 percent.

Under the volume regulation provisions of the Order, the Committee meets each year to adopt a marketing policy for the ensuing year. When the Committee’s marketing policy considerations indicate a need for limiting the quantity of spearmint oil available to the market to establish or maintain orderly marketing conditions, the Committee submits a recommendation to the Secretary of Agriculture for volume regulation.

Volume regulation under the Order is effectuated through the establishment of a salable quantity and allotment percentage applicable to each class of spearmint oil handled in the production area during a marketing year. The salable quantity is the total quantity of each class of oil that handlers may purchase from, or handle on behalf of, producers during a given marketing year. The allotment percentage for each class of oil is derived by dividing the salable quantity by the total industry allotment base for that same class of oil. The total industry allotment base is the aggregate of all allotment base held individually by producers. Producer allotment base is the quantity of each class of spearmint oil that the Committee has determined is

representative of a producer's spearmint oil production. Each producer is allotted a pro rata share of the total salable quantity of each class of spearmint oil each marketing year. Each producer's annual allotment is determined by applying the allotment percentage to the producer's individual allotment base for each applicable class of spearmint oil.

The full Committee met on October 19, 2016, to consider its marketing policy for the 2017–2018 marketing year. At that meeting, the Committee determined that marketing conditions indicated a need for volume regulation of both classes of spearmint oil for the 2017–2018 marketing year. The Committee recommended salable quantities of 774,645 pounds and 1,075,051 pounds, and allotment percentages of 36 percent and 44 percent, respectively, for Scotch and Native spearmint oil. A proposed rule to that effect was published in the **Federal Register** on March 31, 2017 (82 FR 16001). Comments on the proposed rule were solicited from interested persons until May 1, 2017. No comments were received. Subsequently, a final rule establishing the salable quantities and allotment percentages for Scotch and Native spearmint oil for the 2017–2018 marketing year was published in the **Federal Register** on May 25, 2017 (82 FR 24001).

Pursuant to authority contained in §§ 985.50, 985.51, and 985.52, the full eight-member Committee met again on September 25, 2017, and October 25, 2017, to evaluate the current year's volume control regulation. At the meetings, the Committee assessed the current market conditions for spearmint oil in relation to the salable quantities and allotment percentages established for the 2017–2018 marketing year. The Committee considered a number of factors, including the current and projected supply, estimated future demand, production costs, and producer prices for all classes of spearmint oil. The Committee determined that the established salable quantity and allotment percentage in effect for Native spearmint oil for the 2017–2018 marketing year should be increased to take into account the unanticipated rise in market demand for that class of spearmint oil.

At the September 25, 2017, meeting, the Committee recommended increasing the 2017–2018 marketing year Native spearmint oil salable quantity from 1,075,051 pounds to 1,221,696 pounds and the allotment percentage from 44 percent to 50 percent. The recommendation to increase the salable quantity and allotment percentage passed with a vote of seven members in

favor and one opposed. The member opposed to the recommendation favored increasing the Native spearmint oil salable quantity and allotment percentage for the 2017–2018 marketing year, but at an undetermined level lower than what was recommended.

At the October 25, 2017, meeting, the Committee met again to consider an additional increase to the 2017–2018 marketing year salable quantity and allotment percentage for Native spearmint oil. The Committee recommended further increasing the 2017–2018 marketing year Native spearmint oil salable quantity from 1,221,696 pounds to 1,514,902 pounds and the allotment percentage from 50 percent to 62 percent. The recommendation to further increase the salable quantity and allotment percentage passed with a unanimous vote.

This action makes additional amounts of Native spearmint oil available to the market by increasing the salable quantity and allotment percentage previously established under the Order for the 2017–2018 marketing year. This rule increases the Native spearmint oil salable quantity by 439,851 pounds, to 1,514,902 pounds, and raises the allotment percentage 18 percentage points, to 62 percent. Such additional oil will come from releasing Native spearmint oil held by producers in the reserve pool. As of May 31, 2017, the Committee records show that the reserve pool for Native spearmint oil contained 996,050 pounds of oil, an amount considered excessive relative to market conditions.

At both the September and October 2017 meetings, the Committee staff reported that demand for Native spearmint oil has been greater than previously anticipated. Committee records indicate that 2017–2018 marketing year sales to date (945,683 pounds) are tracking fairly closely to sales for the same period in the 2016–2017 marketing year (1,095,112 pounds). However, handlers reported to the Committee that an additional 345,446 pounds of Native spearmint oil are committed to be sold, which would leave a deficit of 216,078 pounds of oil (1,075,051 pounds salable quantity minus 945,683 pounds sold to date and 345,446 pounds committed) to supply the market until May 31, 2018. Another factor that contributed to the short supply was that only 143,011 pounds of salable product carried over from the 2016–2017 marketing year into the 2017–2018 marketing year, which was 46,809 pounds less than expected. The Committee initially estimated in October 2016 that the total available

supply of Native spearmint oil for the 2017–2018 marketing year would be 1,264,871 pounds, but that amount was reduced to 1,218,158 when the smaller carry-in quantity is accounted for.

The Committee initially estimated the trade demand for Native spearmint oil for the 2017–2018 marketing year to be 1,250,000. At the September 25, 2017, meeting, the Committee revised the expected trade demand for the 2017–2018 marketing year to be 1,338,820. At the October 25, 2017, meeting, the Committee further revised the expected trade demand for the 2017–2018 marketing year to 1,600,000 pounds. If realized, trade demand would be 381,842 pounds above the quantity of Native spearmint oil available under the volume control levels implemented in May 2017 (1,218,158 pounds available prior to this rule minus 1,600,000 pounds estimated demand equals a deficit of 381,842 pounds). Without increasing the salable quantity and allotment percentage, the market for Native spearmint oil may be shorted. The increased quantity of Native spearmint oil (439,851 pounds) that will be made available to the market as a result of this rulemaking will ensure that market demand is fully satisfied in the current year and that there would be approximately 20,171 pounds of Native spearmint oil salable inventory available to the market for the start of the 2018–2019 marketing year, which begins on June 1, 2018.

In making the recommendation to increase the salable quantity and allotment percentage of Native spearmint oil, the Committee considered all currently available information on the price, supply, and demand of Native spearmint oil. The Committee also considered reports and other information from handlers and producers in attendance at the meeting. Lastly, the Committee manager presented information and reports that were provided to the Committee staff by handlers and producers.

This rule increases the 2017–2018 marketing year Native spearmint oil salable quantity by 439,851 pounds, to a total of 1,514,902 pounds. However, the Committee expects that not all producers have Native spearmint oil held in reserve. As such, the Committee calculates that 37,796 pounds of the Native spearmint oil salable quantity will go unfulfilled. Therefore, the total supply of Native spearmint oil that the Committee anticipates actually being available to the market over the course of the 2017–2018 marketing year will be increased to 1,620,117 pounds (2017–2018 marketing year salable quantity plus salable carry-in of 143,011 pounds

from the 2016–2017 marketing year minus an unused allotment of 37,796 pounds due to lack of pool oil). Actual sales of Native spearmint oil for the 2016–2017 marketing year totaled 1,287,691 pounds. The 5-year average of Native spearmint oil sales is 1,309,793 pounds.

The Committee estimates that this action will result in 20,171 pounds of salable Native spearmint oil being carried into the 2018–2019 marketing year. While 20,171 pounds is a relatively low quantity of salable Native spearmint oil to end the marketing year, reserve pool oil could be released into the market under a future relaxation of the volume regulation should it be necessary to adequately supply the market prior to the beginning of the 2018–2019 marketing year. The Committee estimates that a total of 1,237,237 pounds of Native spearmint oil will be available from the reserve pool if needed.

As mentioned previously, when the original 2017–2018 marketing policy statement was drafted, handlers estimated the demand for Native spearmint oil for the 2017–2018 marketing year to be 1,250,000 pounds. The Committee's initial recommendation for the establishment of the Native spearmint oil salable quantity and allotment percentage for the 2017–2018 marketing year was based on that estimate. The Committee did not anticipate the increase in demand for Native spearmint oil that the market is currently experiencing and did not make allowances for it when the marketing policy was initially adopted.

At the September 25, 2017, meeting, the Committee revised its estimate of the current trade demand to 1,338,820 pounds, and further increased that estimate to 1,600,000 pounds at the October 25, 2017, meeting. The Committee now believes that the supply of Native spearmint oil available to the market under the initially established salable quantity and allotment percentage will be insufficient to satisfy the current level of demand for oil at reasonable price levels. The Committee further believes that the increase in the salable quantity and allotment percentage is vital to ensuring an adequate supply of Native spearmint oil is available to the market moving forward.

The Committee's stated intent in the use of the Order's volume control regulation is to keep adequate supplies available to meet market needs and to maintain orderly marketing conditions. With that in mind, the Committee developed its recommendation for increasing the Native spearmint oil

salable quantity and allotment percentage for the 2017–2018 marketing year based on the information discussed above, as well as the summary data outlined below.

(A) Initial estimated 2017–2018 Native Allotment Base—2,443,297 pounds. This is the allotment base estimate on which the original 2017–2018 salable quantity and allotment percentage was based.

(B) Revised 2017–2018 Native Allotment Base—2,443,391 pounds. This is 94 pounds more than the initial estimated allotment base of 2,443,297 pounds. The difference is the result of annual adjustments made to the allotment base according to the provisions of the Order.

(C) Initial 2017–2018 Native Allotment Percentage—44 percent. This was unanimously recommended by the Committee on October 19, 2016.

(D) Initial 2017–2018 Native Salable Quantity—1,075,051 pounds. This figure is 44 percent of the original estimated 2017–2018 allotment base of 2,443,297 pounds.

(E) Adjusted Initial 2017–2018 Native Salable Quantity—1,075,092 pounds. This figure reflects the salable quantity actually available at the beginning of the 2017–2018 marketing year. This quantity is derived by applying the initial 44-percent allotment percentage to the revised allotment base of 2,443,391.

(F) Revision to the 2017–2018 Native Salable Quantity and Allotment Percentage:

(1) Increase in the Native Allotment Percentage—18 percent. The Committee recommended an increase of six percentage points at its September 25, 2017, meeting, and a further 12 percentage points at its October 25, 2017, meeting for a total increase of 18 percentage points over the initial Native allotment percentage.

(2) Revised 2017–2018 Native Allotment Percentage—62 percent. This number was derived by adding the increase of 18 percentage points to the initially established 2017–2018 allotment percentage of 44 percent.

(3) Revised 2017–2018 Native Salable Quantity—1,514,902 pounds. This amount is 62 percent of the revised 2017–2018 allotment base of 2,443,391 pounds.

(4) Computed Increase in the 2017–2018 Native Salable Quantity as a Result of the Revision—439,851 pounds. This figure represents 18 percent of the 2017–2018 revised allotment base.

(5) Expected Actual Increase in the Native Spearmint Oil Available to the Market for the 2017–2018 Marketing Year—402,055 pounds. This amount is

based on the Committee's estimation of Native spearmint oil that is actually held by producers in the reserve pool that may enter the market as a result of this action. The Committee estimates that approximately 37,796 pounds of the computed increase will go unfulfilled due to producers who do not have sufficient Native spearmint oil in reserve to utilize their full allotted salable quantity.

Scotch spearmint oil is also regulated by the Order. As mentioned previously, a salable quantity and allotment percentage for Scotch spearmint oil was established in a final rule published in the **Federal Register** on May 25, 2017 (82 FR 24001). At the September 25, 2017, meeting, the Committee considered the current production, inventory, and marketing conditions for Scotch spearmint oil. After receiving reports from the Committee staff and comments from the industry, the consensus of the Committee was that the previously established salable quantity and allotment percentage for Scotch spearmint oil was appropriate for the current market conditions. As such, the Committee took no further action with regards to Scotch spearmint oil for the 2017–2018 marketing year.

This rule relaxes the regulation of Native spearmint oil and allows producers to meet market demand while improving producer returns. In conjunction with the issuance of the proposed rule, the Committee's revised marketing policy statement for the 2017–2018 marketing year has been reviewed by USDA. The Committee's marketing policy statement, a requirement whenever the Committee recommends implementing volume regulations or recommends revisions to existing volume regulations, meets the intent of § 985.50. During its discussion of revisions to the 2017–2018 salable quantities and allotment percentages, the Committee considered: (1) The estimated quantity of salable oil of each class held by producers and handlers; (2) the estimated demand for each class of oil; (3) the estimated production of each class of oil; (4) the total of allotment bases of each class of oil for the current marketing year and the estimated total of allotment bases of each class for the ensuing marketing year; (5) the quantity of reserve oil, by class, in storage; (6) producer prices of oil, including prices for each class of oil; and (7) general market conditions for each class of oil, including whether the estimated season average price to producers is likely to exceed parity. Conformity with USDA's "Guidelines for Fruit, Vegetable, and Specialty Crop

Marketing Orders” has also been reviewed and confirmed.

The increase in the Native spearmint oil salable quantity and allotment percentage will account for the anticipated market needs for that class of oil. In determining anticipated market needs, the Committee considered changes and trends in historical sales, production, and demand.

#### Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are eight spearmint oil handlers subject to regulation under the Order, and approximately 41 producers of Scotch spearmint oil and approximately 94 producers of Native spearmint oil in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$7,500,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000 (13 CFR 121.201).

Based on the SBA’s definition of small entities, the Committee estimates that only two of the eight handlers regulated by the Order could be considered small entities. Most of the handlers are large corporations involved in the international trading of essential oils and the products of essential oils. In addition, the Committee estimates that 12 of the 39 Scotch spearmint oil producers and 31 of the 94 Native spearmint oil producers could be classified as small entities under the SBA definition. Thus, the majority of handlers and producers of Far West spearmint oil may not be classified as small entities.

The use of volume control regulation allows the spearmint oil industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. Without volume control regulation, the supply and price of spearmint oil would likely fluctuate

widely. Periods of oversupply could result in low producer prices and a large volume of oil stored and carried over to future crop years. Periods of undersupply could lead to excessive price spikes and drive end users to source flavoring needs from other markets, potentially causing long-term economic damage to the domestic spearmint oil industry. The Order’s volume control provisions have been successfully implemented in the domestic spearmint oil industry since 1980 and provide benefits for producers, handlers, manufacturers, and consumers.

This final rule increases the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which ends May 31, 2018. The 2017–2018 Native spearmint oil salable quantity was initially established at 1,075,051 pounds and the allotment percentage initially set at 44 percent. This final rule increases the Native spearmint oil salable quantity to 1,514,902 pounds and the allotment percentage to 62 percent.

Based on the information and projections available at the September 25, 2017, and October 25, 2017, meetings, the Committee considered several alternatives to this increase. The Committee considered leaving the salable quantity and allotment percentage unchanged, and also considered other potential levels of increase. The Committee reached its recommendation to increase the salable quantity and allotment percentage for Native spearmint oil after careful consideration of all available information and input from all interested industry participants, and believes that the levels recommended will achieve the desired objectives. Without this increase, the Committee believes the industry will not be able to satisfactorily meet market demand.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order’s information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 (Generic Specialty Crops). No changes are necessary in those requirements as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule relaxes the volume regulation requirements established under the Order. Accordingly, this action will not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil handlers. As with all Federal marketing order programs, reports and forms are

periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, the Committee’s meeting was widely publicized throughout the Far West spearmint oil industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. The September 25, 2017, and October 25, 2017, meetings were public and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on December 1, 2017 (82 FR 56922). Copies of the rule were mailed or sent via facsimile to all Committee members and Far West spearmint oil handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 15-day comment period ending December 18, 2017, was provided to allow interested persons to respond to the proposal.

Ten comments were received from nine commenters in response to the proposed rule. All ten comments were in support of the proposed increase in the salable quantity and allotment percentage. Two of the comments, in addition to supporting the action, also voiced strong interest in USDA effectuating this increase as soon as possible. Accordingly, no changes will be made to the rule as proposed, based on the comments received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because an increase in the Native spearmint oil salable quantity relieves a restriction on the amount of Native spearmint available to the

market. There is pent up demand for additional Far West Native spearmint oil that will not be available under the volume regulation provisions of the Order until this final rule is effective. Handlers want to take advantage of the relaxation of the limitation on the salable quantity of oil as soon as possible, as delay will likely result in the loss of marketing opportunities, in both the short and long term. Native spearmint oil demand that cannot be satisfied from spearmint oil from the Far West production area may be fulfilled from other U.S. production areas or imported product. The loss of immediate business resulting from a delayed implementation of this rule could result in customers entering into long term contracts with other Native spearmint oil providers. There is therefore a risk that delayed implementation of this rule would have a negative impact on Far West spearmint oil handlers' sales in future marketing years.

#### List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

#### PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

- 1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

#### [Subpart Redesignated as Subpart A]

- 2. Redesignate “Subpart-Order Regulating Handling” as “Subpart A-Order Regulating Handling”.

#### [Subpart Redesignated as Subpart B and Amended]

- 3. Redesignate “Subpart-Administrative Rules and Regulations” as subpart B and revise the heading to read as follows:

#### Subpart B—Administrative Requirements

- 4. In § 985.236, revise paragraph (b) to read as follows:

#### § 985.236 Salable quantities and allotment percentages—2017–2018 marketing year.

\* \* \* \* \*

(b) Class 3 (Native) oil—a salable quantity of 1,514,902 pounds and an allotment percentage of 62 percent.

Dated: January 31, 2018.

**Bruce Summers,**

*Acting Administrator, Agricultural Marketing Service.*

[FR Doc. 2018–02264 Filed 2–2–18; 8:45 am]

BILLING CODE 3410–02–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 882

[Docket No. FDA–2018–N–0371]

#### Medical Devices; Neurological Devices; Classification of the Percutaneous Nerve Stimulator for Substance Use Disorders

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the percutaneous nerve stimulator for substance use disorders into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the percutaneous nerve stimulator for substance use disorders' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective February 5, 2018. The classification was applicable on November 15, 2017.

**FOR FURTHER INFORMATION CONTACT:** Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2684, Silver Spring, MD 20993–0002, 301–796–6285, [Eric.Franca@fda.hhs.gov](mailto:Eric.Franca@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the percutaneous nerve stimulator for substance use disorders as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to

the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

**II. De Novo Classification**

On March 17, 2017, Innovative Health Solutions, Inc., submitted a request for De Novo classification of the NSS-2 BRIDGE. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the

establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 15, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.5896. We have named the generic type of device percutaneous nerve stimulator for substance use disorders, and it is identified as a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

**TABLE 1—PERCUTANEOUS NERVE STIMULATOR FOR SUBSTANCE USE DISORDERS RISKS AND MITIGATION MEASURES**

| Identified risks  | Mitigation measures  |
|---|--|
| Adverse tissue reaction .....<br>Electrical, mechanical, or thermal hazards leading to user discomfort or injury. | Biocompatibility evaluation and Labeling. Electromagnetic compatibility testing; Electrical, mechanical, and thermal safety testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling. |
| Infection .....   | Sterility testing, Shelf life testing, and Labeling.   |

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 882**

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

**PART 882—NEUROLOGICAL DEVICES**

■ 1. The authority citation for part 882 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.5896 to subpart F to read as follows:

**§ 882.5896 Percutaneous nerve stimulator for substance use disorders.**

(a) *Identification.* A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.

(b) *Classification.* Class II (special controls). The special controls for this device are:

- (1) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (2) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.
- (3) Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) Sterility testing of the percutaneous components of the device must be performed.
- (6) Shelf life testing must be performed to demonstrate continued

sterility, package integrity, and device functionality over the specified shelf life.

(7) Labeling must include the following:

- (i) A detailed summary of the device technical parameters;
- (ii) A warning stating that the device is only for use on clean, intact skin;
- (iii) Instructions for use, including placement of the device on the patient; and
- (iv) A shelf life.

Dated: January 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-02202 Filed 2-2-18; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG-2018-0009]

RIN 1625-AA08

#### Special Local Regulation; Black Warrior River; Tuscaloosa, AL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation on the Black Warrior River extending the entire width of the river from mile marker 339.0 to mile marker 341.5 in Tuscaloosa, AL. The special local regulation is needed to protect the persons participating in the NCAA Collegiate Rowing Competition marine event. Entry into, transiting through, or exiting from this regulated area is prohibited unless specifically authorized by the Captain of the Port Sector Mobile, or a designated representative.

**DATES:** This rule is effective from 6 a.m. until noon on February 24, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0009 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Kyle D. Berry, Sector Mobile, Waterways Management Division, U.S. Coast Guard; telephone 251-441-5940, email [Kyle.D.Berry@uscg.mil](mailto:Kyle.D.Berry@uscg.mil).

## SUPPLEMENTARY INFORMATION:

### I. Table of Abbreviations

CFR Code of Federal Regulations  
 COTP Captain of the Port Sector Mobile  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 PATCOM Patrol Commander  
 §§ Section  
 U.S.C. United States Code

### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The event sponsors have informed the U.S. Coast Guard that a marine event will occur on February 24, 2018. After gathering all necessary information, including safety needs related to this event, the Coast Guard determined that this special local regulation is necessary for this event. It is impracticable to publish an NPRM because we must establish this special local regulation by February 24, 2018 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is necessary to protect persons and property from the dangers associated with the rowing event.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Sector Mobile (COTP) has determined that potential hazards associated with the rowing event on February 24, 2018 will be a safety concern for anyone within the area of the Black Warrior River between mile markers 339.0 and 341.5. This rule is needed to protect participants, spectators, and other persons and

vessels during the rowing event on navigable waters.

### IV. Discussion of the Rule

This rule establishes a special local regulation on February 24, 2018, which will be enforced between the 6 a.m. and noon. The special local regulation takes place on the Black Warrior River between mile markers 339.0 and 341.5, extending the entire width of the navigable channel. The duration of the regulation is intended to protect participants, spectators, and other persons and vessels before, during, and after the rowing event. No vessel or person will be permitted to enter into, transit through, or exist the regulated area without obtaining permission from the COTP or a designated representative.

The Coast Guard will patrol the regatta area under the direction of the COTP, or a designated representative. A designated representative may be a Coast Guard Patrol Commander (PATCOM). Patrol Commander (PATCOM) means a Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to monitor the rowing area, permit entry into the area, give legally enforceable orders to persons or vessels within the area, and take other actions authorized by the COTP. The PATCOM will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The PATCOM may be contacted on Channel 16 (156.8 MHZ) by the call sign "Coast Guard Patrol Commander."

All persons and vessels not registered with the event sponsor as participants or official patrol vessels are considered spectators. The "official patrol vessels" consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels assigned or approved by the COTP to patrol the regulated area.

Spectator vessels desiring to enter, transit through or within, or exit the regulated area may request permission to do so from the COTP or a PATCOM. When permitted to transit the area vessels must follow restrictions within the regulated area as directed by the Coast Guard, and must operate at a minimum safe navigation speed in a manner which will not endanger participants in the regulated area or any other vessels.

No spectator vessel shall anchor, block, loiter, or impede the through transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

Any spectator vessel may anchor outside the regulated area, but may not anchor in, block, or loiter in a navigable channel. Spectator vessels may be moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event. Such mooring must be complete at least 30 minutes prior to the establishment of the regulated area and remain moored through the duration of the event.

The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property. The COTP or a designated representative will terminate enforcement of the special local regulations at the conclusion of the event.

## V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the regulation. The special local regulation will take place on a 2.5 mile stretch of the Black Warrior River between mile markers

339.0 and 341.5, during a short duration of six hours on February 24, 2018, which is a time of year experiencing lower than normal traffic. Moreover, the Coast Guard will issue Broadcast Notices to Mariners via VHF-FM marine channel 16 about the regulation so that waterway users may plan accordingly for transits during this restriction. The rule also allows vessels to seek permission from the COTP or a designated representative to enter the regulated area.

### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting only six hours on the Black Warrior River between mile markers 339.0 and 341.5. It is categorically excluded from further

review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

#### List of Subjects in 33 CFR Part 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

#### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; 33 CFR 1.05-1.

■ 2. Add § 100.35T08-0009 to read as follows:

#### § 100.35T08-0009 Special Local Regulation; Black Warrior River, Tuscaloosa, AL.

(a) *Regulated area.* All navigable waters of the Black Warrior River between mile markers 339.0 and 341.5, Tuscaloosa, AL.

(b) *Period of enforcement.* This section will be enforced from 6 a.m. until noon on February 24, 2018.

(c) *Special local regulations.* (1) In accordance with the general regulations in § 100.801, entry into, transit within or through, or exit from this area is prohibited unless authorized by the Captain of the Port Sector Mobile (COTP) or a designated representative. A designated representative may be a Patrol Commander (PATCOM). The PATCOM will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Patrol Commander may be contacted on Channel 16 VHF-FM (156.8 MHz) by the call sign "PATCOM".

(2) All persons and vessels not registered with the event sponsor as participants or official patrol vessels are considered spectators. The "official patrol vessels" consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels assigned

or approved by the COTP to patrol the regulated area.

(3) Spectator vessels desiring to transit the regulated area may do so only with prior approval of the COTP or a designated representative and when so directed by that officer will be operated at a minimum safe navigation speed in a manner which will not endanger participants in the regulated area or any other vessels.

(4) No spectator vessel shall anchor, block, loiter, or impede the through transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) Any spectator vessel may anchor outside the regulated area, but may not anchor in, block, or loiter in a navigable channel. Spectator vessels may be moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event. Such mooring must be complete at least 30 minutes prior to the establishment of the regulated area and remain moored through the duration of the event.

(6) The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(7) The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(8) The COTP or a designated representative will terminate enforcement of the special local regulations at the conclusion of the event.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the regulated area as well as any changes in the date and times of enforcement.

Dated: January 26, 2018.

**M.R. Mclellan,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Mobile.*

[FR Doc. 2018-02159 Filed 2-2-18; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

#### 49 CFR Part 171

### General Information, Regulations, and Definitions

#### CFR Correction

In Title 49 of the Code of Federal Regulations, Parts 100 to 177, revised as of October 1, 2017, on page 131, in § 171.8, reinstate the definition of "specification packaging" to read as follows:

#### § 171.8 Definitions and abbreviations.

\* \* \* \* \*

*Specification packaging* means a packaging conforming to one of the specifications or standards for packagings in part 178 or part 179 of this subchapter.

\* \* \* \* \*

[FR Doc. 2018-02303 Filed 2-2-18; 8:45 am]

**BILLING CODE 1301-00-D**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 20

[Docket No. FWS-HQ-MB-2016-0051; FF09M21200-178-FXMB1231099BPP0]

RIN 1018-BB40

### Migratory Bird Hunting; Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2017-18 Season

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** This rule prescribes special migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands. This rule responds to tribal requests for U.S. Fish and Wildlife Service (hereinafter Service or we) recognition of their authority to regulate hunting under established guidelines. This rule allows the establishment of season bag limits and, thus, harvest at levels compatible with populations and habitat conditions.

**DATES:** This rule takes effect on February 5, 2018.

**ADDRESSES:** You may inspect comments received on the special hunting regulations and Tribal proposals during normal business hours at U.S. Fish and Wildlife Headquarters, 5275 Leesburg

Pike, Falls Church, VA 22041-3803, or at <http://www.regulations.gov> at Docket No. FWS-HQ-MB-2016-0051.

**FOR FURTHER INFORMATION CONTACT:** Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church, VA 22041-3803; (703) 358-1967.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Migratory Bird Treaty Act (MBTA) of July 3, 1918 (16 U.S.C. 703 *et seq.*), authorizes and directs the Secretary of the Department of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds, to determine when, to what extent, and by what means such birds or any part, nest, or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported, or transported.

In the August 22, 2017, **Federal Register** (82 FR 39716), we proposed special migratory bird hunting regulations for the 2017-18 hunting season for certain Indian tribes, under the guidelines described in the June 4, 1985, **Federal Register** (50 FR 23467). The guidelines respond to tribal requests for Service recognition of their reserved hunting rights, and for some tribes, recognition of their authority to regulate hunting by both tribal members and nonmembers on their reservations. The guidelines include possibilities for:

(1) On-reservation hunting by both tribal members and nonmembers, with hunting by nontribal members on some reservations to take place within Federal frameworks but on dates different from those selected by the surrounding State(s);

(2) On-reservation hunting by tribal members only, outside of usual Federal frameworks for season dates and length, and for daily bag and possession limits; and

(3) Off-reservation hunting by tribal members on ceded lands, outside of usual framework dates and season length, with some added flexibility in daily bag and possession limits. In all cases, the regulations established under the guidelines must be consistent with the March 10-September 1 closed season mandated by the 1916 Migratory Bird Treaty with Canada.

In the June 10, 2016, **Federal Register** (81 FR 38050), we requested that tribes desiring special hunting regulations in the 2017-18 hunting season submit a proposal including details on:

(1) Harvest anticipated under the requested regulations;

(2) Methods that would be employed to measure or monitor harvest (such as bag checks, mail questionnaires, etc.);

(3) Steps that would be taken to limit level of harvest, where it could be shown that failure to limit such harvest would adversely impact the migratory bird resource; and

(4) Tribal capabilities to establish and enforce migratory bird hunting regulations.

No action is required if a tribe wishes to observe the hunting regulations established by the State(s) in which an Indian reservation is located. We have successfully used the guidelines since the 1985-86 hunting season. We finalized the guidelines beginning with the 1988-89 hunting season (August 18, 1988, **Federal Register** [53 FR 31612]).

The final rule described here is the final in the series of proposed and final rulemaking documents for Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2017-18 Season. Because some tribal seasons began on September 1, before the close of the comment period and finalization of the August 22, 2017, proposed rule (82 FR 39716), we published an interim final rule on August 31, 2017 (82 FR 41344) to allow these tribes to conduct their hunting seasons. In compliance with the MBTA, this rule opened the seasons on the dates set forth in the rule portion of this document, thereby allowing individuals to legally partake in hunting on these lands. Without publication of the interim final rule, hunting of migratory birds on certain Tribal ceded lands as requested by the Tribes would have been prohibited until we concluded with this rulemaking process initiated by the August 22, 2017, proposed rule (82 FR 39716). This new final rule replaces the August 31, 2017, interim final rule.

This rule sets hunting seasons, hours, areas, and limits for migratory game bird species on reservations and ceded territories. This final rule is the culmination of the rulemaking process for the Tribal migratory game bird hunting seasons, which started with the August 22, 2017, proposed rule. This final rule sets the Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2017-18 Season.

**Population Status and Harvest**

Each year we publish various species status reports that provide detailed information on the status and harvest of migratory game birds, including information on the methodologies and results. These reports are available at the address indicated under **FOR**

**FURTHER INFORMATION CONTACT** or from our website at <https://www.fws.gov/birds/surveys-and-data/reports-and-publications/population-status.php>.

We used the following reports: Adaptive Harvest Management, 2017 Hunting Season (August 2016); American Woodcock Population Status, 2016 (August 2016); Band-tailed Pigeon Population Status, 2016 (September 2016); Migratory Bird Hunting Activity and Harvest During the 2014-15 and 2015-16 Hunting Seasons (October 2016); Mourning Dove Population Status, 2016 (August 2016); Status and Harvests of Sandhill Cranes, Mid-continent, Rocky Mountain, Lower Colorado River Valley and Eastern Populations, 2016 (September 2016); and Waterfowl Population Status, 2016 (August 2016).

**Comments and Issues Concerning Tribal Proposals**

For the 2017-18 migratory bird hunting season, we proposed regulations for 24 Tribes or Indian groups that followed the 1985 guidelines and were considered appropriate for final rulemaking. We noted in the August 22 proposed rule that we were proposing seasons for six Tribes who have submitted proposals in past years but from whom we had not yet received proposals this year. We did not receive proposals from five of those Tribes and, therefore, have not included them in this final rule.

The comment period for the August 22 proposed rule closed on September 21, 2017. We received 21 comments on our August 22 proposed rule, which announced proposed seasons for migratory bird hunting by American Indian Tribes. Similar comments were combined and significant comments are addressed below.

*Written Comments:* We received one comment from the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) and three other comments in support of the August 22 proposed rule. GLIFWC expressed support for the content of the proposed regulations listed for the GLIFWC bands and further addressed several potentially new elements of the tribes' migratory bird harvesting rules.

Specifically, GLIFWC appreciated our support for an experimental application of electronic calls to harvest migratory birds and our willingness to approve an experimental application of non-mechanical hand-held nets and snares for the harvest of migratory birds within the 1837 and 1842 Ceded Territories. They pointed out that in order to evaluate the impact that these methods may have, the Tribes have agreed to

require that each hunter engaging in hunting with electronic calls, and hand-held nets or snares, submit a detailed hunter diary at the conclusion of the season. GLIFWC have also agreed to limit the number of permits for electronic calls to 50 hunters, due to concerns articulated by the Service regarding potential effects. They remain confident that the proposal strikes an appropriate balance: Allowing them to hunt migratory birds in an effective and efficient manner, consistent with their reserved treaty rights, while protecting and conserving migratory bird populations for present and future generations. GLIFWC also appreciated our proposal to extend the swan hunting season in the 1837 and 1842 Ceded Territories and establish a sandhill crane hunting season in the 1836 Ceded Territory.

Lastly, GLIFWC addressed the timing of the rulemaking process. They recognized that due to circumstances that may have been out of the Service's control, the final rules may not be issued until the middle of the Tribes' migratory bird hunting season. This delay may foreclose the opportunity for some Tribes to benefit from the proposed rule changes. For example, if we do establish a tribal season for sandhill crane harvesting in the 1836 Ceded Territory, it will be unlikely that hunters will be afforded an opportunity to hunt sandhill cranes in the 2017–18 season, as the migration of sandhill cranes through the 1836 Ceded Territory is likely to have concluded by the time we publish the final rule. The Tribes hope that, in future years, the Service commits to publishing its final rule for Tribes prior to the start of the migratory bird hunting season, noting that the Service consistently issues regulations for State seasons on time.

*Service Response:* Comments noted.

*Written Comments:* The Mississippi Flyway Council (MFC), the Central Flyway Council (CFC), the Wisconsin Department of Natural Resources (WDNR), and 13 other respondents expressed opposition to our proposal to allow GLIFWC the use of electronic calls, night hunting for waterfowl, and the trapping of migratory birds. Opposition expressed included continued concerns about the potential negative impacts to local waterbird populations, the increased potential for take of nongame species, the incompatibility with Federal and State waterfowl management, public safety, potential user conflicts, law-enforcement problems, the fact that electronic calls were not around during the signing of the Treaties, and the potential to place non-tribal hunters in

violation of migratory game bird hunting regulations. We address each of those issues in more detail below.

I. *Allowing the use of electronic duck and goose calls.* The MFC, CFC, and WDNR remain opposed to the proposal as outlined within their prior annual comment letters and noted past Service concerns in **Federal Register** statements over the last several years. As noted in numerous federal documents, they point out that electronic calls are very effective at attracting waterfowl and legal for hunting only in contexts where there is a management objective to produce a level of kill that reduces a local or continental population of migratory birds. Neither of those are objectives in the northern Great Lakes region.

The ceded territory covers one-third of the State of Wisconsin and significant areas of public hunting areas and public waters of Michigan and Minnesota. The commenters believe that the use of electronic calls for waterfowl hunting by tribal hunters could attract waterfowl in a zone of influence that may put any non-tribal hunters within that zone in violation of the law because they are prohibited from being aided by electronic calls in waterfowl hunting. This could effectively close public waters and lands to non-tribal waterfowl hunting where tribal hunters are using electronic calls and create zones of exclusivity. Further, it would not be possible for a tribal hunter to know whether or not a non-tribal hunter would or could be present on a public water or property for waterfowl hunting since most waterfowl hunters find their locations before dawn. In addition to the Federal restrictions on use of electronic calls, Wisconsin waterfowl hunting regulations also prohibit hunting with the “aid” of electronic calls; thus, a non-tribal hunter would be in violation if a tribal hunter was hunting the same general area with electronic calls. Closing these public lands and waters to hunting when they are supported by Pittman-Robertson and State wildlife management funds is inconsistent with their purpose. This situation has the potential to increase conflict among the hunting public creating a safety concern and a challenging law enforcement environment.

II. *Use of hand-net and snares and night hunting of waterfowl.* The MFC was not opposed to the harvest of migratory waterfowl by use of hand-nets and/or snares; however, they did oppose that this would include take of birds at night. The CFC was opposed to the use of hand-held nets and snares, and the WDNR was opposed to night hunting of waterfowl. It has been long established

that sunset is the appropriate closing time for hours in which harvest can occur, relative to migratory birds, to aid in identification and reduce non-target kill as well as promote public safety. WDNR pointed out that although the Service approved a 15-minutes-after-sunset shooting hour for tribal hunters in 2007, and a 30-minutes-after-sunset shooting hour for tribal hunters in 2012 (when 60 minutes was requested), these extensions were made with “trepidation” by the Service. Thus, MFC and CFC opposed these requests when initially proposed, remain opposed to these extensions, and request we return to not allowing any take of migratory bird hunters after the sunset closure of shooting hours for all migratory bird hunters, including tribal members.

III. *Use of hunter diaries.* For both use of electronic calls and hand-nets and snares, GLIFWC has proposed that hunters be required to complete and submit a hunt diary in order to receive a hunting permit the following year. The MFC and WDNR commented that in the past the Service has observed little evidence that these self-reporting requirements have been productive (*i.e.*, tribal swan and sandhill crane seasons). They further point out that in earlier discussions, they had requested that GLIFWC be required to have staff (wardens, biologists) conduct field observations on these “experimental seasons” just as States had been required to do for other experimental seasons, such as early teal seasons. Both restated their desire to require GLIFWC staff to conduct field observation and monitoring on these “experimental seasons” if they are approved.

*Service Response:*

I. *Allowing electronic calls.* In the 1837 and 1842 Treaty Areas, GLIFWC proposes allowing an experimental application of electronic calls with up to 50 Tribal hunters allowed to use the devices. Individuals using electronic calls will be required to obtain a special Tribal permit, complete a hunt diary for each hunt where the devices are used, and submit the hunt diary to the Commission within 2 weeks of the end of the season in order to be eligible to obtain a permit for the following year. GLIFWC will require hunters to record the date, time, and location of each hunt; the number of hunters; the number of each species harvested per hunting event; if other hunters were in the area, any interactions with other hunters; and other information GLIFWC deems appropriate. GLIFWC will then summarize the diary results and submit a report to the Service. Barring unforeseen results, GLIFWC proposes that this experimental application be

replicated for 3 years, after which a full evaluation would be completed.

As we have stated over the last 6 final rules (76 FR 54676, September 1, 2011; 77 FR 54451, September 5, 2012; 78 FR 53218, August 28, 2013; 79 FR 52226, September 3, 2014; 80 FR 52663, September 1, 2015; 81 FR 62404, September 9, 2016), the issue of allowing electronic calls and other electronic devices for migratory game bird hunting has been highly debated and highly controversial over the last 40 years, similar to other prohibited hunting methods. Electronic calls, *i.e.*, the use or aid of recorded or electronic amplified bird calls or sounds, or recorded or electrically amplified imitations of bird calls or sounds to lure or attract migratory game birds to hunters, were federally prohibited in 1957, because of their effectiveness in attracting and aiding the harvest of ducks and geese and because they are generally not considered a legitimate component of hunting (see restriction in 50 CFR 20.21(g)). In 1999, after much debate, the migratory bird regulations were revised to allow the use of electronic calls for the take of light geese (lesser snow geese and Ross geese) during a light-geese-only season when all other waterfowl and crane hunting seasons, excluding falconry, were closed (64 FR 7507, February 16, 1999; 64 FR 71236, December 20, 1999; 73 FR 65926, November 5, 2008). The regulations were also changed in 2006, to allow the use of electronic calls for the take of resident Canada geese during Canada-geese-only September seasons when all other waterfowl and crane seasons, excluding falconry, were closed (71 FR 45964, August 10, 2006). In both instances, these changes were made in order to significantly increase the take of these species due to serious population overabundance, depredation issues, or public health and safety issues, or a combination of these.

In our previous responses on this issue, we have also discussed information stemming from the use of electronic calls during the special light-geese seasons and our conclusions as to its applicability to most other waterfowl species. Given available evidence on the effectiveness of electronic calls, we continue to be concerned about the large biological uncertainty surrounding any widespread use of electronic calls. Additionally, given the fact that tribal waterfowl hunting covered by this rule would occur on ceded lands that are not in the ownership of the Tribes, we remain concerned that the use of electronic calls to take waterfowl could lead to confusion on the part of the public, wildlife-management agencies,

and law enforcement officials in implementing the requirements of 50 CFR part 20. Further, similar to the impacts of baiting, we have some concerns on the uncertain zone of influence range from the use of electronic calls which could potentially increase harvest from non-tribal hunters operating within areas that electronic calls are used during the dates of the general hunt. However, unlike baiting, once the electronic call is removed from an area, the attractant or lure is immediately removed with presumably little to no lingering effects.

Notwithstanding our above concerns, we understand and appreciate GLIFWC's position on this issue, their desire to increase tribal hunter opportunity, harvest, and participation, and the importance that GLIFWC has ascribed to these issues. We further appreciate GLIFWC's latest proposal on the issue. GLIFWC has proposed a limited use of electronic calls under an experimental design with up to only 50 Tribal hunters. Hunters would be required to obtain special permits and complete and submit a hunt diary for each hunt where electronic calls were used. In our recent consultations with them, they have willingly discussed our concerns and all the uncertainties and difficulties surrounding them. Further, given GLIFWC's extremely limited current and expected waterfowl harvest (less than 3,000 ducks and 600 geese) and hunter participation (limited to 50 hunters), our concerns for any potential biological impacts are significantly lessened. Therefore, we agree with the tribes that much of the large uncertainty surrounding any widespread use of electronic calls could be potentially controlled, or significantly lessened, by this very modest experiment.

In that light, we are approving GLIFWC's limited experimental approach with the hope of gaining additional information and knowledge about the use of electronic calls and their effects on waterfowl. Ideally, this limited approach includes utilizing electronic calls both for Canada geese (where they may already be used in some instances) and new efforts for ducks. Important data related to tribal hunter interest, participation, effects on targeted species, and harvest needs to be closely tracked and reported, as GLIFWC has agreed. We conclude that the experimental removal of the electronic call prohibition, with the proposed limited design, is consistent with helping address and answer some of our long-standing concerns, and thus we approve GLIFWC's proposal to allow the experimental use of electronic calls in the 1837 and 1842 Treaty Areas for

any open season for a 3-year experimental period.

*II. Use of hand-held nets and snares.* GLIFWC proposed that we allow tribal members to take migratory birds (primarily waterfowl) with the use of hand-held nets, hand-held snares, and the capturing of birds by hand in the 1837 and 1842 Treaty Areas. GLIFWC's proposal for the use of nets and snares and capturing by hand would include the take of birds at night. Non-attended nets or snares would not be authorized under this proposal. Tribal members using nets or snares to take migratory birds, or taking birds by hand, would be required to obtain a special Tribal permit, complete a hunt diary for each hunt where these methods are used, and submit the hunt diary to the Commission within 2 weeks of the end of the season in order to be eligible to obtain a permit to net migratory birds for the following year. GLIFWC-required information would include the date, time, and location of the hunt; number of hunters; the number of each species harvested per hunting event; and other information GLIFWC deems appropriate. Diary results would then be summarized and documented in a GLIFWC report, which would be submitted to the Service. Barring unforeseen results, GLIFWC proposes that this experimental application be replicated for 3 years, after which a full evaluation would be completed.

Current regulations at 50 CFR part 20 do not allow the use of traps, nets, or snares to capture migratory game birds (see § 20.21(a)), and we are unaware of any current State regulations allowing the use of traps for the capture of resident game birds. While the use of traps or nets for birds is not generally considered a sport-hunting technique, we recognize that their use may be a customary and traditional hunting method by tribal members. Further, GLIFWC's netting and trapping proposal does not allow baiting (which could lead to concerns related to potential disease transmission) or the herding of waterfowl into traps when they are largely flightless, such as during the summer molt. Practices such as these would significantly increase our concerns. As such, and recognizing the importance GLIFWC has placed on this issue, we are not opposed to the trapping of migratory birds, especially given all the GLIFWC-proposed restrictions on their use and the fact that they will be monitored at all times. Thus, we agree with the GLIFWC proposal and conclude that the restrictions they have proposed are appropriate to begin a 3-year experimental evaluation.

III. *Use of hunter diaries.* For both use of electronic calls and hand-nets and snares, GLIFWC has proposed that hunters be required to complete and submit a hunt diary in order to receive a special hunting permit the following year. Despite commenters stating that these tribal self-reporting requirements have not been productive in the past, this methodology, with GLIFWC's commitment, will provide us with useful information to help assess the program's effectiveness, user conflicts, hunter participation, and harvest. Given the relatively small size of the program and the anticipated participation and harvest, we see little need for GLIFWC staff to conduct field observations as States or Flyways (with thousands of hunters and potentially ten of thousands in anticipated harvest) have done for other experimental seasons. However, if we see that either the quality of information being yielded is not sufficient for our purposes or the level of impacts are more than anticipated and may warrant field observers and/or a more rigorous study approach, we will work with GLIFWC to address these issues.

*Written Comments:* Three commenters protested the entire migratory bird hunting regulations process, the killing of all migratory birds, and the status and habitat data on which the migratory bird hunting regulations are based. Two commenters believed certain migratory bird species such as ducks, geese, swans, sandhill cranes, woodcock, and mourning doves should not be hunted.

*Service Response:* Our long-term objectives continue to include providing opportunities to harvest portions of certain migratory game bird populations and to limit harvests to levels compatible with each population's ability to maintain healthy, viable numbers. Further, there exists a long history of establishing hunting seasons for migratory game bird species such as waterfowl, cranes, woodcock, doves, and migratory shore and upland game birds. Tribes, such as those included in this final rule, have hunted these species before and since the inception of our establishment of migratory game bird hunting seasons. These seasons are culturally important to them, and applicable treaties allow for hunting of these species.

Having taken into account the zones of temperature and the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds, we conclude that the hunting seasons provided for herein are compatible with the current status of migratory bird populations and long-

term population goals. Additionally, we are obligated to, and do, give serious consideration to all information received as public comment. We continue to conclude that the current Flyway-Council system of migratory bird management is one of the longest, most successful examples of State-Federal cooperative management since its establishment in 1952. Likewise, the establishment of special tribal migratory bird hunting regulations has been a successful Federal-Tribal partnership since 1988. However, as always, we continue to seek new ways to improve the process.

#### Required Determinations

##### *Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs*

This final rule is not subject to the requirements of Executive Order (E.O.) 13771 (82 FR 9339, February 3, 2017) because this final rule establishes annual harvest limits related to routine hunting or fishing.

##### *National Environmental Policy Act (NEPA) Consideration*

The programmatic document, "Second Final Supplemental Environmental Impact Statement: Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (EIS 20130139)," filed with the Environmental Protection Agency (EPA) on May 24, 2013, addresses NEPA compliance by the Service for issuance of the annual framework regulations for hunting of migratory game bird species. We published a notice of availability in the **Federal Register** on May 31, 2013 (78 FR 32686), and our Record of Decision on July 26, 2013 (78 FR 45376). We also address NEPA compliance for waterfowl hunting frameworks through the annual preparation of separate environmental assessments, the most recent being "Duck Hunting Regulations for 2017–18," with its corresponding April 7, 2017, finding of no significant impact. The programmatic document as well the separate environmental assessments are available on our website at <https://www.fws.gov/birds/index.php> or from the address indicated under the caption **FOR FURTHER INFORMATION CONTACT.**

##### *Endangered Species Act Consideration*

Section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), provides that, "The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act" (and) shall "insure that any

action authorized, funded, or carried out . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat. . . ." Consequently, we conducted formal consultations to ensure that actions resulting from these regulations would not likely jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of their critical habitat. Findings from these consultations are included in a biological opinion, which concluded that the regulations are not likely to jeopardize the continued existence of any endangered or threatened species. Additionally, these findings may have caused modification of some regulatory measures previously proposed, and the final frameworks reflect any such modifications. Our biological opinions resulting from this section 7 consultation are public documents available for public inspection at the address indicated under **ADDRESSES.**

##### *Regulatory Planning and Review (Executive Orders 12866 and 13563)*

E.O. 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has reviewed this rule and has determined that this rule is significant because it would have an annual effect of \$100 million or more on the economy.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

An economic analysis was prepared for the 2013–14 season. This analysis was based on data from the 2011 National Hunting and Fishing Survey, the most recent year for which data are available (see discussion under *Regulatory Flexibility Act*, below). We used this analysis again for the 2017–18 season. This analysis estimated consumer surplus for three alternatives

for duck hunting (estimates for other species are not quantified due to lack of data). The alternatives are (1) issue restrictive regulations allowing fewer days than those issued during the 2012–13 season, (2) issue moderate regulations allowing more days than those in alternative 1, and (3) issue liberal regulations identical to the regulations in the 2012–13 season. For the 2013–14 season, we chose Alternative 3, with an estimated consumer surplus across all flyways of \$317.8–\$416.8 million. We also chose alternative 3 for the 2009–10, the 2010–11, the 2011–12, the 2012–13, the 2014–15, the 2015–16, the 2016–17, and the 2017–18 seasons. The 2013–14 analysis is part of the record for this rule and is available at <http://www.regulations.gov> at Docket No. FWS–HQ–MB–2016–0051.

#### *Regulatory Flexibility Act*

The annual migratory bird hunting regulations have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). We analyzed the economic impacts of the annual hunting regulations on small business entities in detail as part of the 1981 cost-benefit analysis. This analysis was revised annually from 1990–95. In 1995, the Service issued a Small Entity Flexibility Analysis (Analysis), which was subsequently updated in 1996, 1998, 2004, 2008, and 2013. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The 2013 Analysis was based on the 2011 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend approximately \$1.5 billion at small businesses in 2013. Copies of the Analysis are available upon request from the Division of Migratory Bird Management (see **FOR FURTHER INFORMATION CONTACT**) or from <http://www.regulations.gov> at Docket No. FWS–HQ–MB–2016–0051.

#### *Small Business Regulatory Enforcement Fairness Act*

This final rule is a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. For the reasons outlined above, this rule will have an annual effect on the economy of \$100 million or more. However, because this rule establishes hunting seasons, we do not plan to defer the effective date under the exemption contained in 5 U.S.C. 808(1).

#### *Paperwork Reduction Act*

This rule does not contain any new information collection that requires approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has reviewed and approved the information collection requirements associated with migratory bird surveys and assigned the following OMB control numbers:

- 1018–0019—North American Woodcock Singing Ground Survey (expires 5/31/2018).
- 1018–0023—Migratory Bird Surveys (expires 8/31/2020). Includes Migratory Bird Harvest Information Program, Migratory Bird Hunter Surveys, Sandhill Crane Survey, and Parts Collection Survey.

#### *Unfunded Mandates Reform Act*

We have determined and certify, in compliance with the requirements of the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of \$100 million or more in any given year on local or State government or private entities. Therefore, this rule is not a “significant regulatory action” under the Unfunded Mandates Reform Act.

#### *Civil Justice Reform—Executive Order 12988*

The Department, in promulgating this rule, has determined that this rule will not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of E.O. 12988.

#### *Takings Implication Assessment*

In accordance with E.O. 12630, this rule, authorized by the Migratory Bird Treaty Act, does not have significant takings implications and does not affect any constitutionally protected property rights. This rule will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. In fact, this rule allows hunters to exercise otherwise unavailable privileges and, therefore, reduces restrictions on the use of private and public property.

#### *Energy Effects—Executive Order 13211*

E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. While this rule is a significant regulatory action under E.O. 12866, it is not expected to adversely affect energy supplies, distribution, or use. Therefore, this action is not a significant energy

action and no Statement of Energy Effects is required.

#### *Government-to-Government Relationship With Tribes*

In accordance with the President's memorandum of April 29, 1994, “Government-to-Government Relations with Native American Tribal Governments” (59 FR 22951), E.O. 13175, and 512 DM 2, we have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects on Indian trust resources. We have consulted with Tribes affected by this rule.

#### *Federalism Effects*

Due to the migratory nature of certain species of birds, the Federal Government has been given responsibility over these species by the Migratory Bird Treaty Act. We annually prescribe frameworks from which the States make selections regarding the hunting of migratory birds, and we employ guidelines to establish special regulations on Federal Indian reservations and ceded lands. This process preserves the ability of the States and tribes to determine which seasons meet their individual needs. Any State or Indian tribe may be more restrictive than the Federal frameworks at any time. The frameworks are developed in a cooperative process with the States and the Flyway Councils. This process allows States to participate in the development of frameworks from which they will make selections, thereby having an influence on their own regulations. These rules do not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. Therefore, in accordance with E.O. 13132, these regulations do not have significant federalism effects and do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

#### **Regulations Promulgation**

The rulemaking process for migratory game bird hunting, by its nature, operates under a time constraint as seasons must be established each year or hunting seasons remain closed. However, we intend that the public be provided extensive opportunity for public input and involvement in compliance with Administrative Procedure Act requirements. Thus, when the preliminary proposed rulemaking was published, we established what we concluded were the

longest periods possible for public comment and the most opportunities for public involvement. Further, after establishment of the final frameworks, Tribes need sufficient time to conduct their own public processes to select season dates and limits; to communicate those selections to us; and to establish and publicize the necessary regulations and procedures to implement their decisions. Thus, if there were a delay in the effective date of these regulations after this final rulemaking, Tribes might not be able to meet their own administrative needs and requirements. For the reasons cited above, we find that “good cause” exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, and this final rule will take effect immediately upon publication.

Accordingly, with each participating Tribe having had an opportunity to participate in selecting the hunting seasons desired for its reservation or ceded territory on those species of migratory birds for which open seasons are now prescribed, and consideration having been given to all other relevant matters presented, certain sections of title 50, chapter I, subchapter B, part 20, subpart K, are hereby amended as set forth below.

#### List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, part 20, subchapter B, chapter I of title 50 of the Code of Federal Regulations is amended as follows:

#### PART 20—MIGRATORY BIRD HUNTING

- 1. Revise the authority citation for part 20 to read as follows:

**Authority:** 16 U.S.C. 703 *et seq.*, and 16 U.S.C. 742a–j.

(**Note:** The following hunting regulations provided for by 50 CFR 20.110 will not appear in the Code of Federal Regulations because of their seasonal nature).

- 2. Section 20.110 is revised to read as follows:

#### § 20.110 Seasons, limits, and other regulations for certain Federal Indian reservations, Indian Territory, and ceded lands.

Unless specifically provided for below, all of the regulations contained in 50 CFR part 20 apply to the seasons listed herein.

(a) [Reserved.]

(b) *Confederated Salish and Kootenai Tribes, Flathead Indian Reservation,*

*Pablo, Montana (Tribal Members and Nontribal Hunters).*

#### Tribal Members Only

##### Ducks (Including Mergansers)

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* The Tribe does not have specific bag and possession restrictions for Tribal members. The season on harlequin duck is closed.

##### Coots

*Season Dates:* Same as ducks.

*Daily Bag and Possession Limits:* Same as ducks.

##### Geese

*Season Dates:* Same as ducks.

*Daily Bag and Possession Limits:* Same as ducks.

##### Nontribal Hunters

*Ducks (Including Mergansers)*

*Season Dates:* Open September 30, 2017, through January 7, 2018, and open January 13 through 17, 2018.

##### Scaup

*Season Dates:* Open September 30 through December 24, 2017.

*Daily Bag and Possession Limits:* Seven ducks, including no more than two hen mallards, one pintail, three scaup (when open), two canvasback, and two redheads. The possession limit is three times the daily bag limit.

##### Coots

*Season Dates:* Same as ducks.

*Daily Bag and Possession Limits:* 25 and 25, respectively.

##### Geese

*Dark Geese*

*Season Dates:* Open September 30, 2017, through January 7, 2018, and open January 13 through 17, 2018.

*Daily Bag and Possession Limits:* 4 and 12, respectively.

*Light Geese*

*Season Dates:* Same as for dark geese.

*Daily Bag and Possession Limits:* 20 and 60, respectively.

*General Conditions:* Tribal and nontribal hunters must comply with all basic Federal migratory bird hunting regulations contained in 50 CFR part 20 regarding manner of taking. In addition, shooting hours are one-half hour before sunrise to one-half hour after sunset, and each waterfowl hunter 16 years of age or older must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the stamp face.

Special regulations established by the Confederated Salish and Kootenai Tribes also apply on the reservation.

(c) *Fond du Lac Band of Lake Superior Chippewa Indians, Cloquet, Minnesota (Tribal Members Only).*

#### Ducks

*1854 and 1837 Ceded Territories*

*Season Dates:* Begin September 9 and end November 30, 2017.

*Daily Bag Limit:* 18 ducks, including no more than 12 mallards (only 3 of which may be hens), 9 black ducks, 9 scaup, 9 wood ducks, 9 redheads, 9 pintails, and 9 canvasbacks.

*Reservation*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 12 ducks, including no more than 8 mallards (only 2 of which may be hens), 6 black ducks, 6 scaup, 6 redheads, 6 pintails, 6 wood ducks, and 6 canvasbacks.

#### Mergansers

*1854 and 1837 Ceded Territories*

*Season Dates:* Begin September 9 and end November 30, 2017.

*Daily Bag Limit:* 15 mergansers, including no more than 6 hooded mergansers.

*Reservation*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 10 mergansers, including no more than 4 hooded mergansers.

#### Canada Geese

*1854 and 1837 Ceded Territories*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 20 geese.

*Reservation*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 20 geese.

#### Coots and Common Moorhens (Common Gallinules)

*1854 and 1837 Ceded Territories*

*Season Dates:* Begin September 9 and end November 30, 2017.

*Daily Bag Limit:* 20 coots and common moorhens, singly or in the aggregate.

*Reservation*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 20 coots and common moorhens, singly or in the aggregate.

**Sandhill Cranes: 1854 and 1837 Ceded Territories**

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* Two sandhill cranes. Crane carcass tags are required prior to hunting.

**Sora and Virginia Rails***All Areas*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 25 sora and Virginia rails, singly or in the aggregate.

**Common Snipe***All Areas*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* Eight common snipe.

**Woodcock***All Areas*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* Three woodcock.

**Mourning Doves***All Areas*

*Season Dates:* Begin September 1 and end November 30, 2017.

*Daily Bag Limit:* 30 mourning doves.

**General Conditions**

1. While hunting waterfowl, a tribal member must carry on his/her person a valid Ceded Territory License.

2. Shooting hours for migratory birds are one-half hour before sunrise to one-half hour after sunset.

3. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the provisions of Chapter 10 of the Model Off-Reservation Code. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel Federal requirements in 50 CFR part 20 as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting.

4. Band members in each zone will comply with State regulations providing for closed and restricted waterfowl hunting areas.

5. There are no possession limits for migratory birds. For purposes of enforcing bag limits, all migratory birds in the possession or custody of band members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as having been taken on-reservation. All migratory birds that fall on reservation lands will

not count as part of any off-reservation bag or possession limit.

(d) *Grand Traverse Band of Ottawa and Chippewa Indians, Suttons Bay, Michigan (Tribal Members Only).*

**Ducks**

*Season Dates:* Open September 1, 2017, through January 20, 2018.

*Daily Bag Limits:* 35 ducks, which may include no more than 8 pintail, 4 canvasback, 8 black ducks, 5 hooded merganser, 8 wood ducks, 8 redheads, and 20 mallards (only 10 of which may be hens).

**Canada and Snow Geese**

*Season Dates:* Open September 1, 2017, through February 15, 2018.

*Daily Bag Limits:* 15 geese.

**Other Geese (White-Fronted Geese and Brant)**

*Season Dates:* Open September 20 through December 30, 2017.

*Daily Bag Limits:* Five geese.

**Sora Rails, Common Snipe, and Woodcock**

*Season Dates:* Open September 1 through November 14, 2017.

*Daily Bag Limits:* 10 rails, 10 snipe, and 5 woodcock.

**Mourning Doves**

*Season Dates:* Open September 1 through November 14, 2017.

*Daily Bag Limits:* 15 mourning doves.

**Sandhill Crane**

*Season Dates:* Open September 1 through November 14, 2017.

*Daily Bag Limits:* 3 sandhill crane, with a season limit of 10.

*General Conditions:* A valid Grand Traverse Band Tribal license is required and must be in possession before taking any wildlife. Shooting hours for migratory birds are one-half hour before sunrise to one-half hour after sunset. All other basic regulations contained in 50 CFR part 20 are valid. Other tribal regulations apply, and may be obtained at the tribal office in Suttons Bay, Michigan.

(e) *Great Lakes Indian Fish and Wildlife Commission, Odanah, Wisconsin (Tribal Members Only).*

The 2017–18 waterfowl hunting season regulations apply to all treaty areas (except where noted):

**Ducks**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag Limits:* 50 ducks in the 1837 and 1842 Treaty Area; 30 ducks in the 1836 Treaty Area.

**Mergansers**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag Limits:* 10 mergansers.

**Geese**

*Season Dates:* Begin September 1 and end December 31, 2017. In addition, any portion of the ceded territory that is open to State-licensed hunters for goose hunting outside of these dates will also be open concurrently for tribal members.

*Daily Bag Limits:* 20 geese in aggregate.

**Other Migratory Birds****Coots and Common Moorhens (Common Gallinules)**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag Limits:* 20 coots and common moorhens (common gallinules), singly or in the aggregate.

**Sora and Virginia Rails**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag and Possession Limits:* 20, singly, or in the aggregate, 25.

**Common Snipe**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag Limits:* 16 common snipe.

**Woodcock**

*Season Dates:* Begin September 5 and end December 31, 2017.

*Daily Bag Limits:* 10 woodcock.

**Mourning Dove: 1837 and 1842 Ceded Territories Only**

*Season Dates:* Begin September 1 and end November 29, 2017.

*Daily Bag Limits:* 15 mourning doves.

**Sandhill Cranes: 1837 and 1842 Ceded Territories Only**

*Season Dates:* Begin September 1 and end December 31, 2017.

*Daily Bag Limits:* 2 cranes.

**Swans: 1837 and 1842 Ceded Territories Only**

*Season Dates:* Begin November 1 and end December 31, 2017.

*Daily Bag Limits:* 2 swans. All harvested swans must be registered by presenting the fully-feathered carcass to a tribal registration station or GLIFWC warden. If the total number of trumpeter swans harvested reaches 10, the swan season will be closed by emergency tribal rule.

**General Conditions**

A. All tribal members are required to obtain a valid tribal waterfowl hunting permit.

B. Except as otherwise noted, tribal members are required to comply with tribal codes that are no less restrictive than the model ceded territory conservation codes approved by Federal courts in the *Lac Courte Oreilles v. State of Wisconsin (Voigt)* and *Mille Lacs Band v. State of Minnesota* cases. Chapter 10 in each of these model codes regulates ceded territory migratory bird hunting. Both versions of Chapter 10 parallel Federal requirements as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting. They also automatically incorporate by reference the Federal migratory bird regulations.

C. Particular regulations of note include:

1. Nontoxic shot is required for all waterfowl hunting by tribal members.

2. Tribal members in each zone must comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

3. There are no possession limits, with the exception of 2 swans (in the aggregate) and 25 rails (in the aggregate). For purposes of enforcing bag limits, all migratory birds in the possession and custody of tribal members on ceded lands are considered to have been taken on those lands unless tagged by a tribal or State conservation warden as taken on reservation lands. All migratory birds that fall on reservation lands do not count as part of any off-reservation bag or possession limit.

4. There are no shell limit restrictions.

5. Hunting hours are from 30 minutes before sunrise to 30 minutes after sunset, except that, within the 1837 and 1842 ceded territories hunters may use non-mechanical nets or snares that are operated by hand to take those birds subject to an open hunting season at any time. Hunters shall be permitted to capture, without the aid of other devices (*i.e.*, by hand) and immediately kill birds subject to an open season, regardless of time of day. See #7 below for further explanation.

6. An experimental application of electronic calls (e-calls) will be implemented in the 1837 and 1842 ceded territories. Up to 50 tribal hunters will be allowed to use e-calls. Individuals using e-calls will be required to obtain a special permit; they will be required to complete a hunt diary for each hunt where e-calls are used; and they will be required to submit the hunt diary to the Commission within two (2) weeks of the end of the season in order to be eligible

to obtain an e-call permit for the following year. Required information will include the date, time and location of the hunt, number of hunters, the number of each species harvested per hunting event, if other hunters were in the area, any interactions with other hunters, and other information deemed appropriate. Diary results will be summarized and documented in a Commission report, which will be submitted to the Service. Barring unforeseen results, this experimental application would be replicated for 3 years, after which a full evaluation would be completed.

7. Within the 1837 and 1842 ceded territories, tribal members will be allowed to use non-mechanical hand-operated nets (*i.e.*, throw/cast nets or hand-held nets typically used to land fish) and/or hand-operated snares, and may chase and capture migratory birds without the aid of hunting devices (*i.e.*, by hand). At this time, non-attended nets or snares shall not be authorized under this regulation. Tribal members using nets or snares to take migratory birds, or taking birds by hand, will be required to obtain a special permit; they will be required to complete a hunt diary for each hunt where these methods are used; and they will be required to submit the hunt diary to the Commission within two (2) weeks of the end of the season in order to be eligible to obtain a permit to net migratory birds for the following year. Required information will include the date, time and location of the hunt, number of hunters, the number of each species harvested per hunting event, and other information deemed appropriate. Diary results will be summarized and documented in a Commission report, which will be submitted to the Service. Barring unforeseen results, this experimental application would be replicated for 3 years, after which a full evaluation would be completed.

(f) *Jicarilla Apache Tribe, Jicarilla Indian Reservation, Dulce, New Mexico (Tribal Members and Nontribal Hunters)*.

#### **Ducks (Including Mergansers)**

*Season Dates:* Open October 14 through November 30, 2017.

*Daily Bag and Possession Limits:* The daily bag limit is seven, including no more than two hen mallards, two pintail, two redheads, two canvasback, and three scaup. The possession limit is three times the daily bag limit.

#### **Canada Geese**

*Season Dates:* Open October 8 through November 30, 2017.

*Daily Bag and Possession Limits:* Two and six, respectively.

*General Conditions:* Tribal and nontribal hunters must comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or older must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the stamp face. Special regulations established by the Jicarilla Tribe also apply on the reservation.

(g) *Kalispel Tribe, Kalispel Reservation, Usk, Washington (Tribal Members and Nontribal Hunters)*.

#### **Nontribal Hunters on Reservation**

##### **Geese**

*Season Dates:* Open September 9 through September 10, 2017; open September 16 through September 17, 2017; and open October 1, 2017, through January 8, 2018. During these periods, days to be hunted are specified by the Kalispel Tribe. Nontribal hunters should contact the Tribe for more detail on hunting days.

*Daily Bag and Possession Limits:* 5 Canada geese for the early season, and 6 light geese and 4 dark geese, for the late season. The daily bag limit is 2 brant (when the State's season is open) and is in addition to dark goose limits for the late-season. The possession limit is twice the daily bag limit.

##### **Ducks**

*Season Dates:* Open September 23, 2017, through September 24, 2017; open September 29, through September 30, 2017; and open October 1, 2017, through January 8, 2018.

##### **Scaup**

*Season Dates:* Open October 1, 2017, through December 25, 2017.

*Daily Bag and Possession Limits:* 7 ducks, including no more than 2 female mallards, 1 pintail, 2 canvasback, 3 scaup (when open), and 2 redheads. The possession limit is twice the daily bag limit.

#### **Tribal Hunters Within Kalispel Ceded Lands**

##### **Ducks**

*Season Dates:* Open October 10, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* 7 ducks, including no more than 2 female mallards, 1 pintail, 2 canvasback, 3 scaup, and 2 redheads. The possession limit is twice the daily bag limit.

**Geese**

*Season Dates:* Open September 10, 2017, through January 31, 2018.

*Daily Bag Limit:* 20 light geese and 4 dark geese. The daily bag limit is 2 brant and is in addition to dark goose limits.

*General:* Tribal members must possess a validated Migratory Bird Hunting and Conservation Stamp and a tribal ceded lands permit.

(h) *Klamath Tribe, Chiloquin, Oregon (Tribal Members Only).*

**Ducks and Coots**

*Season Dates:* Open October 7, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* 9 and 18, respectively.

**Geese**

*Season Dates:* Open October 7, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* 9 and 18, respectively.

*General:* Nontoxic shot is required. Use of live decoys, bait, and commercial use of migratory birds are prohibited. Waterfowl may not be pursued or taken while using motorized craft. Shooting hours are one-half hour before sunrise to one-half hour after sunset.

(i) *Leech Lake Band of Ojibwe, Cass Lake, Minnesota (Tribal Members Only).*

**Ducks**

*Season Dates:* Open September 16 through December 31, 2017.

*Daily Bag Limits:* 10 ducks, including no more than 5 pintail, 5 canvasback, and 5 black ducks.

**Geese**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limits:* 10 geese.

*General:* Possession limits are twice the daily bag limits. Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required. Use of live decoys, bait, and commercial use of migratory birds are prohibited. Waterfowl may not be pursued or taken while using motorized craft.

(j) *Little River Band of Ottawa Indians, Manistee, Michigan (Tribal Members Only).*

**1836 Ceded Territory and Tribal Reservation****Ducks, Coots, and Gallinules**

*Season Dates:* Open September 15, 2017, through January 26, 2018.

*Daily Bag Limits:* 12 ducks, including no more than 6 mallards (2 of which may be hens), 3 black ducks, 3 redheads, 3 wood ducks, 2 pintail, 1 bufflehead, 1 hooded merganser, and 2 canvasback. Five coot and five gallinule.

**Canada Geese**

*Season Dates:* Open September 1, 2017, through February 4, 2018.

*Daily Bag Limit:* Five.

**White-Fronted Geese, Brant, and Snow Geese**

*Season Dates:* Open September 8 through December 10, 2017.

*Daily Bag Limit:* Five.

**Woodcock, Mourning Doves, Snipe, and Sora and Virginia Rails**

*Season Dates:* Open September 1 through November 12, 2017.

*Daily Bag Limit:* 5 woodcock and 10 each of the other species.

*General Conditions Are as Follows*

A. All tribal members will be required to obtain a valid tribal resource card and 2017–18 hunting license.

B. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel all Federal regulations contained in 50 CFR part 20. Shooting hours will be from one-half hour before sunrise to sunset.

C. Particular regulations of note include:

(1) Nontoxic shot will be required for all waterfowl hunting by tribal members.

(2) Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

D. Tribal members hunting in Michigan will comply with tribal codes that contain provisions parallel to Michigan law regarding duck blinds and decoys.

E. Possession limits are twice the daily bag limits.

(k) *The Little Traverse Bay Bands of Odawa Indians, Petoskey, Michigan (Tribal Members Only).*

**Ducks**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* 20 ducks, including no more than 5 hen mallards, 5 black ducks, 5 redheads, 5 wood ducks, 5 pintail, 5 scaup, and 5 canvasback.

**Mergansers**

*Season Dates:* Open September 15, 2017, through January 31, 2018.

*Daily Bag Limits:* 10 mergansers, including no more than 5 hooded mergansers.

**Coots and Gallinules**

*Season Dates:* Open September 15 through December 31, 2017.

*Daily Bag Limit:* 20.

**Canada Geese**

*Season Dates:* Open September 1, 2017, through February 8, 2018.

*Daily Bag Limit:* 20 in the aggregate.

**Sora and Virginia Rails**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limit:* 20.

**Snipe**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limit:* 16.

**Mourning Doves**

*Season Dates:* Open September 1 through November 14, 2017.

*Daily Bag Limit:* 15.

**Woodcock**

*Season Dates:* Open September 1 through December 1, 2017.

*Daily Bag Limit:* 10.

**Sandhill Cranes**

*Season Dates:* Open September 1 through December 1, 2017.

*Daily Bag Limit:* 1.

*General:* Possession limits are twice the daily bag limits.

(l) *Lower Brule Sioux Tribe, Lower Brule Reservation, Lower Brule, South Dakota (Tribal Members and Nontribal Hunters).*

**Tribal Members****Ducks, Mergansers, and Coots**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Six ducks, including no more than two hen mallard and five mallards total, two pintail, two redheads, two canvasback, three wood ducks, three scaup, two bonus teal during the first 16 days of the season, and one mottled duck Coot daily bag limit is 15. Merganser daily bag limit is five, including no more than two hooded mergansers. The possession limit is three times the daily bag limit.

**Canada Geese**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 6 and 18, respectively.

**White-Fronted Geese**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Two and six, respectively.

**Light Geese**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag Limit:* 20.

#### **Nontribal Hunters**

##### **Ducks (Including Mergansers and Coots)**

*Season Dates:* Open October 7, 2017, through January 11, 2018.

*Daily Bag and Possession Limits:* Six ducks, including five mallards (no more of which can be two hen mallard), three scaup, two canvasback, two redheads, three wood ducks, one mottled duck, one pintail, and two bonus blue-winged teal during October 7, through October 22, 2017. Coot daily bag limit is 15. Merganser daily bag limit is five, including no more than two hooded mergansers. The possession limit is three times the daily bag limit.

##### **Canada Geese**

*Season Dates:* Open October 28, 2017, through February 11, 2018.

*Daily Bag and Possession Limits:* 6 and 18, respectively.

##### **White-Fronted Geese**

*Season Dates:* Open October 28, 2017, through January 23, 2018.

*Daily Bag and Possession Limits:* Two and six, respectively.

##### **Light Geese**

*Season Dates:* Open October 28, 2017, through February 11, 2018.

*Daily Bag and Possession Limits:* 50 and no possession limit.

*General Conditions:* All hunters must comply with the basic Federal migratory bird hunting regulations in 50 CFR part 20, including the use of steel shot and shooting hours. Nontribal hunters must possess a validated Migratory Bird Hunting and Conservation Stamp. The Lower Brule Sioux Tribe has an official Conservation Code that hunters must adhere to when hunting in areas subject to control by the Tribe.

(m) [Reserved.]

(n) *Makah Indian Tribe, Neah Bay, Washington (Tribal Members).*

##### **Band-Tailed Pigeons**

*Season Dates:* Open September 22 through October 23, 2017.

*Daily Bag Limit:* Two band-tailed pigeons.

##### **Ducks and Coots**

*Season Dates:* Open September 23, 2017, through January 28, 2018.

*Daily Bag Limit:* Seven ducks including no more than five mallards (only two of which can be a hen), one redhead, one pintail, three scaup, and one canvasback. The seasons on wood duck and harlequin are closed. The coot daily bag limit is 25.

#### **Geese**

*Season Dates:* Open September 23, 2017, through January 28, 2018.

*Daily Bag Limit:* Four, including no more than one brant. The seasons on Aleutian and dusky Canada geese are closed.

##### *General Conditions*

All other Federal regulations contained in 50 CFR part 20 apply. The following restrictions also apply:

1. As per Makah Ordinance 44, only shotguns may be used to hunt any species of waterfowl. Additionally, shotguns must not be discharged within 0.25 miles of an occupied area.

2. Hunters must be eligible, enrolled Makah tribal members and must carry their Indian Treaty Fishing and Hunting Identification Card while hunting. No tags or permits are required to hunt waterfowl.

3. The Cape Flattery area is open to waterfowl hunting, except in designated wilderness areas, or within 1 mile of Cape Flattery Trail, or in any area that is closed to hunting by another ordinance or regulation.

4. The use of live decoys and/or baiting to pursue any species of waterfowl is prohibited.

5. Steel or bismuth shot only for waterfowl is allowed; the use of lead shot is prohibited.

6. The use of dogs is permitted to hunt waterfowl.

7. Shooting hours for all species of waterfowl are one-half hour before sunrise to sunset.

8. Open hunting areas are: GMUs 601 (Hoko), a portion of the 602 (Dickey) encompassing the area north of a line between Norwegian Memorial and east to Highway 101, and 603 (Pysht).

(o) *Navajo Nation, Navajo Indian Reservation, Window Rock, Arizona (Tribal Members and Nontribal Hunters).*

##### **Band-Tailed Pigeons**

*Season Dates:* Open September 1 through September 30, 2017.

*Daily Bag and Possession Limits:* 5 and 10 pigeons, respectively.

##### **Mourning Doves**

*Season Dates:* Open September 1 through September 30, 2017.

*Daily Bag and Possession Limits:* 10 and 20 doves, respectively.

##### **Ducks (Including Mergansers and Coots)**

*Season Dates:* Open September 23, 2017, through January 7, 2018.

##### **Scaup**

*Season Dates:* Open September 23 through December 17, 2017.

##### *Daily Bag and Possession Limits:*

Seven ducks, including no more than two hen mallards, one mottled duck, two canvasback, three scaup (when open), two redheads, and one pintail. Coot daily bag limit is 25. Merganser daily bag limit is seven. The possession limit is three times the daily bag limit.

##### **Canada Geese**

*Season Dates:* Open September 23, 2017, through January 7, 2018.

*Daily Bag and Possession Limits:* 4 and 12, respectively.

*General Conditions:* Tribal and nontribal hunters will comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20, regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the face. Special regulations established by the Navajo Nation also apply on the reservation.

(p) *Oneida Tribe of Indians of Wisconsin, Oneida, Wisconsin (Tribal Members Only).*

##### **Ducks (Including Mergansers)**

*Season Dates:* Open September 16 through December 3, 2017.

*Daily Bag and Possession Limits:* Six, including no more than six mallards (three hen mallards), six wood ducks, one redhead, two pintail, and one hooded merganser. The possession limit is twice the daily bag limit.

##### **Geese**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag and Possession Limits:* 5 Canada geese with a possession limit of 10. A seasonal quota of 500 birds is adopted. If the quota is reached before the season concludes, the season will be closed at that time.

##### **Woodcock**

*Season Dates:* Open September 2 through November 5, 2017.

*Daily Bag and Possession Limits:* Two and four woodcock, respectively.

##### **Doves**

*Season Dates:* Open September 2 through November 5, 2017.

*Daily Bag and Possession Limits:* 10 and 20 doves, respectively.

*General Conditions:* Tribal member shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontribal members hunting on the Reservation or on lands under the jurisdiction of the Tribe must comply with all State of Wisconsin regulations,

including season dates, shooting hours, and bag limits, which differ from tribal member seasons. Tribal members and nontribal members hunting on the Reservation or on lands under the jurisdiction of the Tribe will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, with the following exceptions: Tribal members are exempt from the purchase of the Migratory Waterfowl Hunting and Conservation Stamp (Duck Stamp); and shotgun capacity is not limited to three shells.

(q) *Point No Point Treaty Council, Kingston, Washington (Tribal Members Only)*.

#### **Jamestown S'Klallam Tribe**

##### **Ducks**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Seven ducks, including no more than one harlequin duck per season.

##### **Geese**

*Season Dates:* Open September 9, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Four geese, and may include no more than three light geese. The season on dusky Canada geese is closed. Possession limit is twice the daily bag limit.

##### **Brant**

*Season Dates:* Open January 10 through January 25, 2018.

*Daily Bag and Possession Limits:* Two and four, respectively.

##### **Coots**

*Season Dates:* Open September 13, 2017, through February 1, 2018.

*Daily Bag and Possession Limits:* 25 and 50 coots, respectively.

##### **Mourning Doves**

*Season Dates:* Open September 13, 2017, through January 18, 2018.

*Daily Bag and Possession Limits:* 10 and 20 doves, respectively.

##### **Snipe**

*Season Dates:* Open September 13, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 8 and 16 snipe, respectively.

##### **Band-Tailed Pigeons**

*Season Dates:* Open September 13, 2017, through January 18, 2018.

*Daily Bag and Possession Limits:* Two and four pigeons, respectively.

#### **Port Gamble S'Klallam Tribe**

##### **Ducks**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Seven ducks, including no more than one harlequin duck per season.

##### **Geese**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Four geese, and may include no more than three light geese. The season on dusky Canada geese is closed. Possession limit is twice the daily bag limit.

##### **Brant**

*Season Dates:* Open November 9, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* Two and four, respectively.

##### **Coots**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 7 and 14 coots, respectively.

##### **Mourning Doves**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* 10 and 20 doves, respectively.

##### **Snipe**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 8 and 16 snipe, respectively.

##### **Band-Tailed Pigeons**

*Season Dates:* Open September 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* Two and four pigeons, respectively.

*General:* Tribal members must possess a tribal hunting permit from the Point No Point Tribal Council pursuant to tribal law. Hunting hours are from one-half hour before sunrise to sunset. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(r) *The Saginaw Chippewa Indian Tribe of Michigan, Isabella Reservation, Mt. Pleasant, Michigan (Tribal Members Only)*.

##### **Mourning Doves**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limit:* 25 doves.

##### **Ducks**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* 20, including no more than 5 hen mallard, 5 wood duck, 5 black duck, 5 pintail, 5 redhead, 5 scaup, and 5 canvasback.

##### **Mergansers**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limit:* 10, including no more than 5 hooded mergansers.

#### **Canada Geese**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limit:* 20 in the aggregate.

#### **Coots and Gallinule**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limit:* 20 in the aggregate.

#### **Woodcock**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* 10.

#### **Common Snipe**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* 16.

#### **Sora and Virginia Rails**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* 20 in the aggregate.

#### **Sandhill Crane**

*Season Dates:* Open September 1, 2017, through January 31, 2018.

*Daily Bag Limits:* One.

*General:* Possession limits are twice the daily bag limits except for rails, of which the possession limit equals the daily bag limit (20). Tribal members must possess a tribal hunting permit from the Saginaw Tribe pursuant to tribal law. Shooting hours are one-half hour before sunrise until one-half hour after sunset. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(s) *Sault Ste. Marie Tribe of Chippewa Indians, Sault Ste. Marie, Michigan (Tribal Members Only)*.

#### **Mourning Doves**

*Season Dates:* Open September 1 through November 14, 2017.

*Daily Bag Limit:* 10 doves.

#### **Teal**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limits:* 20 in the aggregate.

#### **Ducks**

*Season Dates:* Open September 15 through December 31, 2017.

*Daily Bag Limits:* 20, including no more than 10 mallards (only 5 of which may be hens), 5 canvasback, 5 black duck, and 5 wood duck.

#### **Mergansers**

*Season Dates:* Open September 15 through December 31, 2017.

*Daily Bag Limit:* 10 in the aggregate.

**Geese**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limit:* 20 in the aggregate.

**Coots and Gallinule**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limit:* 20 in the aggregate.

**Woodcock**

*Season Dates:* Open September 2 through December 1, 2017.

*Daily Bag Limits:* 10.

**Common Snipe**

*Season Dates:* Open September 15 through December 31, 2017.

*Daily Bag Limits:* 16.

**Sora and Virginia Rails**

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag Limits:* 20 in the aggregate.

*General:* Possession limits are twice the daily bag limits except for rails, of which the possession limit equals the daily bag limit (20). Tribal members must possess a tribal hunting permit from the Sault Ste. Marie Tribe pursuant to tribal law. Shooting hours are one-half hour before sunrise until one-half hour after sunset. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(t) *Shoshone-Bannock Tribes, Fort Hall Indian Reservation, Fort Hall, Idaho (Nontribal Hunters).*

**Ducks, Including Mergansers**

*Duck Season Dates:* Open October 7, 2017, through January 19, 2018.

*Scaup Season Dates:* Open October 7, 2017, through December 31, 2017.

*Daily Bag and Possession Limits:* Seven ducks and mergansers, including no more than two hen mallards, one pintail, three scaup (when open), two canvasback, and two redheads. The possession limit is three times the daily bag limit.

**Coots**

*Season Dates:* Same as ducks.

*Daily Bag and Possession Limits:* 25 coots. The possession limit is three times the daily bag limit.

**Common Snipe**

*Season Dates:* Same as ducks.

*Daily Bag and Possession Limits:* 8 and 24 snipe, respectively.

**Canada Geese**

*Season Dates:* Open October 7, 2017, through January 19, 2018.

*Daily Bag and Possession Limits:* 4 and 12, respectively.

**White-Fronted Geese**

*Season Dates:* Open October 7, 2017, through January 19, 2018.

*Daily Bag and Possession Limits:* 10 and 30, respectively.

**Light Geese**

*Season Dates:* Open October 7, 2017, through January 19, 2018.

*Daily Bag and Possession Limits:* 20 and 60, respectively.

*General Conditions:* Nontribal hunters must comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or older must possess a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the stamp face. Other regulations established by the Shoshone-Bannock Tribes also apply on the reservation.

(u) [Reserved.]

(v) [Reserved.]

(w) [Reserved.]

(x) *Stillaguamish Tribe of Indians, Arlington, Washington (Tribal Members Only).*

**Common Snipe**

*Season Dates:* Open October 1, 2017, through January 31, 2018.

*Daily Bag and Possession Limits:* 10 and 30, respectively.

**Ducks**

*Season Dates:* Open October 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 10 ducks. The possession limit is three times the daily bag limit.

**Coots**

*Season Dates:* Open October 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 25 coots. The possession limit is three times the daily bag limit.

**Geese**

*Season Dates:* Open October 1, 2017, through March 10, 2018.

*Daily Bag and Possession Limits:* 6 and 18, respectively. The season on brant is closed.

*General Conditions:* Tribal members hunting on lands will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, which will be enforced by the Stillaguamish Tribal Law Enforcement. Tribal members are required to use steel shot or a nontoxic shot as required by Federal regulations.

(y) *Swinomish Indian Tribal Community, LaConner, Washington (Tribal Members Only).*

**Ceded Territory and Swinomish Reservation****Ducks and Mergansers**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* 20 and 40, respectively.

**Canada Geese**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* 10 and 20 geese, respectively.

**Brant**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* 5 and 10 brant, respectively.

**Coots**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* 25 and 75 coots, respectively.

**Mourning Dove**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* 15 and 30 mourning dove, respectively.

**Band-Tailed Pigeon**

*Season Dates:* Open September 1, 2017, through March 9, 2018.

*Daily Bag and Possession Limits:* Three and six band-tailed pigeon, respectively.

(z) *The Tulalip Tribes of Washington, Tulalip Indian Reservation, Marysville, Washington (Tribal Members Only).*

**Ducks and Mergansers**

*Season Dates:* Open September 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* Seven ducks, including no more than two hen mallards, one pintail, two canvasback, three scaup, and two redheads. Possession limit is twice the daily bag limit.

**Geese**

*Season Dates:* Open September 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* Seven geese, including no more than four cackling and dusky Canada geese. Possession limit is twice the daily bag limit.

**Brant**

*Season Dates:* Open September 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* Two and four brant, respectively.

**Coots**

*Season Dates:* Open September 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* 25 and 25 coots, respectively.

### Snipe

*Season Dates:* Open September 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* 8 and 16 snipe, respectively.

*General Conditions:* All tribal hunters must have a valid Tribal identification card on his or her person while hunting. All nontribal hunters must obtain and possess while hunting a valid Tulalip Tribe hunting permit and be accompanied by a Tulalip Tribal member. Shooting hours are one-half hour before sunrise to sunset, and steel shot is required for all migratory bird hunting. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(aa) *Upper Skagit Indian Tribe, Sedro Woolley, Washington (Tribal Members Only).*

### Mourning Doves

*Season Dates:* Open September 1 through December 31, 2017.

*Daily Bag and Possession Limits:* 12 and 15 mourning doves, respectively.

### Ducks

*Season Dates:* Open October 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* 15 and 20, respectively.

### Coots

*Season Dates:* Open October 1, 2017, through February 15, 2018.

*Daily Bag and Possession Limits:* 20 and 30, respectively.

### Geese

*Season Dates:* Open October 1, 2017, through February 28, 2018.

*Daily Bag and Possession Limits:* 7 and 10 geese, respectively.

### Brant

*Season Dates:* Open November 1 through 10, 2017.

*Daily Bag and Possession Limits:* Two and two, respectively.

*General Conditions:* Tribal members must have the tribal identification and harvest report card on their person to hunt. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, except shooting hours would be 15 minutes before official sunrise to 15 minutes after official sunset.

(bb) *Wampanoag Tribe of Gay Head, Aquinnah, Massachusetts (Tribal Members Only).*

### Teal

*Season Dates:* Open October 9, 2017, through February 17, 2018.

*Daily Bag Limits:* 10 teal.

### Ducks

*Season Dates:* Open October 9, 2017, through February 17, 2018.

*Daily Bag Limits:* Six ducks, including no more than four hen mallards, six black ducks, four mottled ducks, one fulvous whistling duck, four mergansers, three scaup, two hooded merganser, three wood ducks, one canvasback, two redheads, and two pintail. The season is closed for harlequin ducks.

### Sea Ducks

*Season Dates:* Open October 2, 2017, through February 17, 2018.

*Daily Bag Limits:* Seven ducks including no more than four of any one species (only one of which may be a hen eider).

### Woodcock

*Season Dates:* Open October 9 through November 25, 2017.

*Daily Bag Limits:* Three woodcock.

### Canada Geese

*Season Dates:* Open September 4 through 16, 2017, and open October 23, 2017, through February 17, 2018.

*Daily Bag Limits:* Eight Canada geese.

### Snow Geese

*Season Dates:* Open September 4 through 16, 2017, and open November 20, 2017, through February 17, 2018.

*Daily Bag Limits:* 15 snow geese.

### Sora and Virginia Rails

*Season Dates:* Open September 4 through November 4, 2017.

*Daily Bag Limits:* 5 sora and 10 Virginia rails.

### Snipe

*Season Dates:* Open September 4 through December 9, 2017.

*Daily Bag Limits:* Eight snipe.

*General Conditions:* Shooting hours are one-half hour before sunrise to sunset. Nontoxic shot is required. All other basic Federal migratory bird hunting regulations contained in 50 CFR part 20 will be observed.

(cc) *White Earth Band of Ojibwe, White Earth, Minnesota (Tribal Members Only).*

### Ducks

*Season Dates:* Open September 9 through December 17, 2017.

*Daily Bag Limit for Ducks:* 10 ducks, including no more than 2 female mallards, 1 pintail, and 1 canvasback.

### Mergansers

*Season Dates:* Open September 9 through December 17, 2017.

*Daily Bag Limit for Mergansers:* Five mergansers, including no more than two hooded mergansers.

### Geese

*Season Dates:* Open September 1 through December 15, 2017.

*Daily Bag Limit:* 12 geese through September 23, and 5 thereafter.

### Coots

*Season Dates:* Open September 1 through November 30, 2017.

*Daily Bag Limit:* 20 coots.

### Snipe

*Season Dates:* Open September 1 through November 30, 2017.

*Daily Bag Limit:* 10 snipe.

### Mourning Dove

*Season Dates:* Open September 1 through November 30, 2017.

*Daily Bag Limit:* 25 mourning dove.

### Woodcock

*Season Dates:* Open September 1 through November 30, 2017.

*Daily Bag Limit:* 10 woodcock.

### Rail

*Season Dates:* Open September 1 through November 30, 2017.

*Daily Bag Limit:* 25 rail.

*General Conditions:* Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required. All other basic Federal migratory bird hunting regulations contained in 50 CFR part 20 will be observed.

(dd) *White Mountain Apache Tribe, Fort Apache Indian Reservation, Whiteriver, Arizona (Tribal Members and Nontribal Hunters).*

### Band-Tailed Pigeons (Wildlife Management Unit 10 and Areas South of Y-70 and Y-10 in Wildlife Management Unit 7, Only)

*Season Dates:* Open September 1 through 15, 2017.

*Daily Bag and Possession Limits:* Three and six pigeons, respectively.

### Mourning Doves (Wildlife Management Unit 10 and Areas South of Y-70 and Y-10 in Wildlife Management Unit 7, Only)

*Season Dates:* Open September 1 through 15, 2017.

*Daily Bag and Possession Limits:* 10 and 20 doves, respectively.

### Ducks and Mergansers

*Season Dates:* Open October 14, 2017, through January 28, 2018.

**Scaup**

*Season Dates:* Open November 4, 2017, through January 28, 2018.

*Daily Bag Limits:* Seven including no more than two redheads, one pintail, three scaup (when open), seven mallards (including no more than two hen mallards), and two canvasback.

*Possession Limits:* Twice the daily bag limit.

**Coots**

*Season Dates:* Open October 14, 2017, through January 28, 2018.

*Daily Bag and Possession Limits:* 25 and 50, respectively.

**Canada Geese**

*Season Dates:* Open October 14, 2017, through January 28, 2018.

*Daily Bag and Possession Limits:* Three and six Canada geese, respectively.

*General Conditions:* All nontribal hunters hunting band-tailed pigeons and mourning doves on Reservation lands shall have in their possession a valid White Mountain Apache Daily or Yearly Small Game Permit. In addition to a small game permit, all nontribal hunters hunting band-tailed pigeons must have in their possession a White Mountain Special Band-tailed Pigeon Permit. Other special regulations established by the White Mountain Apache Tribe apply on the reservation. Tribal and nontribal hunters will comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 regarding shooting hours and manner of taking.

Dated: January 16, 2018.

**Jason Larrabee,**

*Principal Deputy Assistant Secretary for Fish and Wildlife and Parks, Exercising the Authority of the Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2018-02203 Filed 2-2-18; 8:45 am]

**BILLING CODE 4333-15-P**

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 665**

[Docket No. 170915903-8077-02]

RIN 0648-XF706

**Pacific Island Fisheries; 2017 Hawaii Kona Crab Annual Catch Limit and Accountability Measure**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Final specification.

**SUMMARY:** In this final rule, NMFS specifies an annual catch limit (ACL) for 2017 of 3,500 lb for Hawaii Kona crab, and an accountability measure (AM) to correct or mitigate any overages of the catch limit. The ACL and AM support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

**DATES:** The final specification is effective March 7, 2018. The final specification is applicable from January 1, 2017, through December 31, 2017.

**ADDRESSES:** The Fishery Ecosystem Plan for the Hawaiian Archipelago is available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808-522-8220, fax 808-522-8226, or <http://www.wpcouncil.org>. Copies of the environmental analysis and other supporting documents for this action, identified by NOAA-NMFS-2017-0012, are available at <http://www.regulations.gov/>

*#!docketDetail;D=NOAA-NMFS-2017-0012*, or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd. Bldg. 176, Honolulu, HI 96818.

**FOR FURTHER INFORMATION CONTACT:** Sarah Ellgen, NMFS PIR Sustainable Fisheries, 808-725-5173.

**SUPPLEMENTARY INFORMATION:** NMFS is specifying an ACL of 3,500 lb of Hawaii Kona crab for fishing year 2017. NMFS proposed this specification on December 20, 2017 (82 FR 60366), and the final specification does not differ from the proposed. The 2017 fishing year began on January 1 and ended on December 31.

The Council recommended the ACL based on a recommended acceptable biological catch of 3,500 lb from its Scientific and Statistical Committee, and the results of an October 2015 stock assessment. The stock assessment found that the Hawaii Kona crab stock had reached an overfished status (<50 percent of  $B_{MSY}$ , biomass at maximum sustainable yield) in 2006, and was likely still overfished in 2010. The assessment also included biomass projections for 2010-2030 under three commercial landings scenarios: Zero lb, 7,000 lb, and 8,000 lb.

At a constant 7,000-lb annual commercial harvest rate, the assessment estimated that Kona crab biomass would increase above 50 percent of  $B_{MSY}$  by 2030, but due to uncertainty, there was a chance that stock biomass could potentially decline to zero lb by 2020. In developing the ACL, the Council also considered information indicating a 50:50 male to female landings ratio, and

information suggesting that crabs disentangled from Kona crab may have injuries that could result in mortality rates as high as 100 percent if limbs are lost. Therefore, to meet the objective of rebuilding stock biomass to levels >50 percent of  $B_{MSY}$ , and limit total fishing mortality to 7,000 lb, the Council recommended an ACL of 3,500 lb. NMFS is planning to complete a benchmark assessment for Hawaii Kona crab in 2019, which could be available for management use in fishing year 2020.

As an AM, NMFS will apply a 3-year average catch to evaluate fishery performance against the ACL. Specifically, NMFS will use the average catch of fishing years 2015, 2016, and 2017, to evaluate fishery performance against the 2017 ACL. If, after the end of the fishing year, NMFS and the Council determine that the 3-year average catch exceeded the specified ACL, NMFS and the Council will reduce the ACL for that fishery by the amount of the overage in the subsequent year. The Council recommended an AM based on multi-year average catch data to reduce the influence of inter-annual variability in catch estimates in evaluating fishery performance against the ACL.

You may review additional background information on this action in the preamble to the proposed specification (82 FR 60366; December 20, 2017); we do not repeat that information here.

**Comments and Responses**

The comment period for the proposed specification ended on January 4, 2018. NMFS received two public comments that were not relevant to this rulemaking.

**Changes From the Proposed Specification**

There are no changes in the final specification from the proposed specification.

**Classification**

The Regional Administrator, NMFS PIR, determined that this action is necessary for the conservation and management of Pacific Island fisheries, and that it is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small

entities. NMFS published the factual basis for certification in the proposed specification, and does not repeat it here. NMFS did not receive comments regarding the certification and has no reason to think that anything has changed to affect it. As a result, a final regulatory flexibility analysis is not required, and one was not prepared.

This action is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: January 30, 2018.

**Samuel D. Rauch, III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

[FR Doc. 2018-02162 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

[Docket No. 161020985-7181-02]

RIN 0648-XF979

**Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pollock in the Bering Sea and Aleutian Islands**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule.

**SUMMARY:** NMFS is reallocating the projected unused amounts of the Aleut Corporation's and the Community Development Quota pollock directed

fishing allowances from the Aleutian Islands subarea to the Bering Sea subarea directed fisheries. These actions are necessary to provide opportunity for harvest of the 2018 total allowable catch of pollock, consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), February 5, 2018, until the effective date of the final 2018 and 2019 harvest specifications for Bering Sea and Aleutian Islands (BSAI) groundfish, unless otherwise modified or superseded through publication of a notification in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In the Aleutian Islands subarea, the portion of the 2018 pollock total allowable catch (TAC) allocated to the Aleut Corporation's directed fishing allowance (DFA) is 14,700 metric tons (mt) and the Community Development Quota (CDQ) DFA is 1,900 mt as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 26, 2017), and as adjusted by an inseason

adjustment (82 FR 60329, December 20, 2017).

As of January 17, 2018, the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that 12,200 mt of Aleut Corporation's DFA and 1,900 mt of pollock CDQ DFA in the Aleutian Islands subarea will not be harvested. Therefore, in accordance with § 679.20(a)(5)(iii)(B)(4), NMFS reallocates 12,200 mt of Aleut Corporation's DFA and 1,900 mt of pollock CDQ DFA from the Aleutian Islands subarea to the 2018 Bering Sea subarea allocations. The 1,900 mt of pollock CDQ DFA is added to the 2018 Bering Sea CDQ DFA. The remaining 12,200 mt of pollock is apportioned to the AFA Inshore sector (50 percent), AFA catcher/processor sector (40 percent), and the AFA mothership sector (10 percent). The 2018 Bering Sea subarea pollock incidental catch allowance remains at 47,888 mt. As a result, the 2018 harvest specifications for pollock in the Aleutian Islands subarea included in the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 26, 2017) are revised as follows: 2,500 mt to Aleut Corporation's DFA and 0 mt to CDQ DFA. Furthermore, pursuant to § 679.20(a)(5), Table 5 of the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 26, 2017), as adjusted by the inseason adjustment (82 FR 60329, December 20, 2017), is revised to make 2018 pollock allocations consistent with this reallocation. This reallocation results in adjustments to the 2018 Aleut Corporation and CDQ pollock allocations established at § 679.20(a)(5).

**TABLE 5—FINAL 2018 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) <sup>1</sup>**

[Amounts are in metric tons]

| Area and sector                           | 2018 Allocations | 2018 A season <sup>1</sup> |                                | 2018 B season <sup>1</sup> |
|---|------------------|----------------------------|--------------------------------|----------------------------|
|   |                  | A season DFA               | SCA harvest limit <sup>2</sup> | B season DFA               |
| Bering Sea subarea TAC <sup>1</sup>       | 1,378,441        | n/a                        | n/a                            | n/a                        |
| CDQ DFA                                   | 138,334          | 62,250                     | 38,734                         | 76,084                     |
| ICA <sup>1</sup>                          | 47,888           | n/a                        | n/a                            | n/a                        |
| Total Bering Sea non-CDQ DFA              | 1,192,219        | 536,499                    | 333,821                        | 655,720                    |
| AFA Inshore                               | 596,109          | 268,249                    | 166,911                        | 327,860                    |
| AFA Catcher/Processors <sup>3</sup>       | 476,888          | 214,599                    | 133,529                        | 262,288                    |
| Catch by C/Ps                             | 436,352          | 196,358                    | n/a                            | 239,994                    |
| Catch by CVs <sup>3</sup>                 | 40,535           | 18,241                     | n/a                            | 22,294                     |
| Unlisted C/P Limit <sup>4</sup>           | 2,384            | 1,073                      | n/a                            | 1,311                      |
| AFA Motherships                           | 119,222          | 53,650                     | 33,382                         | 65,572                     |
| Excessive Harvesting Limit <sup>5</sup>   | 208,638          | n/a                        | n/a                            | n/a                        |
| Excessive Processing Limit <sup>6</sup>   | 357,666          | n/a                        | n/a                            | n/a                        |
| Aleutian Islands subarea ABC              | 40,788           | n/a                        | n/a                            | n/a                        |
| Aleutian Islands subarea TAC <sup>1</sup> | 4,900            | n/a                        | n/a                            | n/a                        |
| CDQ DFA                                   | 0                | 0                          | n/a                            | 0                          |

TABLE 5—FINAL 2018 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) <sup>1</sup>—Continued

[Amounts are in metric tons]

| Area and sector                          | 2018 Allocations | 2018 A season <sup>1</sup> |                                | 2018 B season <sup>1</sup> |
|--|------------------|----------------------------|--------------------------------|----------------------------|
|  |                  | A season DFA               | SCA harvest limit <sup>2</sup> | B season DFA               |
| ICA .....                                | 2,400            | 1,200                      | n/a                            | 1,200                      |
| Aleut Corporation .....                  | 2,500            | 2,500                      | n/a                            | 0                          |
| Area harvest limit <sup>7</sup> .....    | n/a              | n/a                        | n/a                            | n/a                        |
| 541 .....                                | 12,236           | n/a                        | n/a                            | n/a                        |
| 542 .....                                | 6,118            | n/a                        | n/a                            | n/a                        |
| 543 .....                                | 2,039            | n/a                        | n/a                            | n/a                        |
| Bogoslof District ICA <sup>8</sup> ..... | 450              | n/a                        | n/a                            | n/a                        |

<sup>1</sup> Pursuant to § 679.20(a)(5)(i)(A), the Bering Sea subarea pollock, after subtracting the CDQ DFA (10 percent) and the ICA (3.9 percent), is allocated as a DFA as follows: inshore sector—50 percent, catcher/processor sector (C/P)—40 percent, and mothership sector—10 percent. In the Bering Sea subarea, 45 percent of the DFA is allocated to the A season (January 20–June 10) and 55 percent of the DFA is allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(2)(i) through (iii), the annual Aleutian Islands pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the ICA (2,400 mt), is allocated to the Aleut Corporation for a pollock directed fishery. In the Aleutian Islands subarea, the A season is allocated up to 40 percent of the ABC and the B season is allocated the remainder of the pollock directed fishery.

<sup>2</sup> In the Bering Sea subarea, pursuant to § 679.20(a)(5)(i)(C), no more than 28 percent of each sector’s annual DFA may be taken from the SCA before noon, April 1.

<sup>3</sup> Pursuant to § 679.20(a)(5)(i)(A)(4), not less than 8.5 percent of the DFA allocated to listed catcher/processors shall be available for harvest only by eligible catcher vessels delivering to listed catcher/processors.

<sup>4</sup> Pursuant to § 679.20(a)(5)(i)(A)(4)(iii), the AFA unlisted catcher/processors are limited to harvesting not more than 0.5 percent of the catcher/processors sector’s allocation of pollock.

<sup>5</sup> Pursuant to § 679.20(a)(5)(i)(A)(6), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

<sup>6</sup> Pursuant to § 679.20(a)(5)(i)(A)(7), NMFS establishes an excessive processing share limit equal to 30.0 percent of the sum of the non-CDQ pollock DFAs.

<sup>7</sup> Pursuant to § 679.20(a)(5)(iii)(B)(6), NMFS establishes harvest limits for pollock in the A season in Area 541 of no more than 30 percent, in Area 542 of no more than 15 percent, and in Area 543 of no more than 5 percent of the Aleutian Islands pollock ABC.

<sup>8</sup> Pursuant to § 679.22(a)(7)(i)(B), the Bogoslof District is closed to directed fishing for pollock. The amounts specified are for ICA only and are not apportioned by season or sector.

**Note:** Seasonal or sector apportionments may not total precisely due to rounding.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of AI pollock. Since the pollock fishery opened January 20, 2018, it is important to immediately inform the industry as to the final Bering Sea subarea pollock allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery; allow the industry to plan for the fishing season and avoid potential disruption to the fishing fleet as well as processors; and provide opportunity to harvest increased seasonal pollock allocations while value is optimum. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data

only became available as of January 26, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: January 31, 2018.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2018–02235 Filed 2–2–18; 8:45 am]

**BILLING CODE 3510–22–P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

[Docket No. 160920866–7167–02]

RIN 0648–XF941

**Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Non-American Fisheries Act Crab Vessels Operating as Catcher Vessels Using Pot Gear in the Western Regulatory Area of the Gulf of Alaska**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific cod by non-American Fisheries Act (AFA) crab vessels that are subject to sideboard limits, and operating as catcher vessels (CVs) using pot gear, in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2018 Pacific cod sideboard limit established for non-AFA crab vessels that are operating as

CVs using pot gear in the Western Regulatory Area of the GOA.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), February 1, 2018, through 1200 hours, A.l.t., June 10, 2018.

**FOR FURTHER INFORMATION CONTACT:** Obren Davis, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The A season allowance of the 2018 Pacific cod sideboard limit established for non-AFA crab vessels, and that are operating as CVs using pot gear in the Western Regulatory Area of the GOA, is 338 metric tons (mt), as established by the final 2017 and 2018 harvest specifications for groundfish of the GOA (82 FR 12032, February 27, 2017) and one inseason adjustment (82 FR 60327, December 20, 2017).

In accordance with § 680.22(e)(2)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the A season allowance of the 2018 Pacific cod sideboard limit established for non-AFA crab vessels that are operating as CVs using pot gear in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a sideboard directed fishing allowance of 328 mt, and is setting aside the remaining 10 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 680.22(e)(3), the Regional Administrator finds that this sideboard directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by non-AFA crab vessels that are operating as CVs using pot gear in the Western Regulatory Area of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### **Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment

pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the sideboard directed fishing closure of Pacific cod for non-AFA crab vessels that are subject to sideboard limits, and that are operating as CVs using pot gear in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 30, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 680.22 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: January 31, 2018.

**Emily H. Menashes,**  
*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2018-02248 Filed 1-31-18; 4:15 pm]

**BILLING CODE 3510-22-P**

# Proposed Rules

Federal Register

Vol. 83, No. 24

Monday, February 5, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## BUREAU OF CONSUMER FINANCIAL PROTECTION

### 12 CFR Part 1081

[Docket No. CFPB–2018–0002]

#### Request for Information Regarding Bureau Rules of Practice for Adjudication Proceedings

**AGENCY:** Bureau of Consumer Financial Protection.

**ACTION:** Request for information.

**SUMMARY:** The Bureau of Consumer Financial Protection (Bureau) is seeking comments and information from interested parties to assist the Bureau in considering whether and how to amend the Bureau's Rules of Practice for Adjudication Proceedings.

**DATES:** Comments must be received by April 6, 2018.

**ADDRESSES:** You may submit responsive information and other comments, identified by Docket No. CFPB–2018–0002, by any of the following methods:

- *Electronic:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* [FederalRegisterComments@cfpb.gov](mailto:FederalRegisterComments@cfpb.gov). Include Docket No. CFPB–2018–0002 in the subject line of the message.

- *Mail:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

- *Hand Delivery/Courier:* Monica Jackson Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

*Instructions:* The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Please note the number of the question on which you are commenting at the top of each response (you do not need to answer all questions). Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments

electronically. In general, all comments received will be posted without change to <http://www.regulations.gov>. In addition, comments will be available for public inspection and copying at 1700 G St NW, Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. eastern standard time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions in response to this request for information, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

**FOR FURTHER INFORMATION CONTACT:** For general inquiries and submission process questions, please call Monica Jackson at (202) 435–7275.

**SUPPLEMENTARY INFORMATION:** The Consumer Financial Protection Act of 2010 (Act) required the Bureau to prescribe rules establishing such procedures as may be necessary to carry out hearings and adjudications conducted pursuant to 12 U.S.C. 5563. 12 U.S.C. 5563(e). On July 28, 2011, the Bureau published an interim final rule seeking comment and prescribing rules establishing such hearings and procedures, with the exception of rules relating to the issuance of a temporary cease-and-desist order (TCDO) pursuant to section 1053(c) of the Act. 76 FR 45338 (July 28, 2011). The Bureau responded to comments received and published a final rule on June 29, 2012. 77 FR 39058 (June 29, 2012). This rule was codified at 12 CFR part 1081, subparts A–D. The Bureau published an interim final rule seeking comment and prescribing rules on TCDOs on September 26, 2013. 78 FR 59163 (Sept. 26, 2013). The Bureau received a single comment on this rule. Following consideration of the comment, the Bureau adopted the interim final rule without change on June 18, 2014. 79 FR 34622 (June 18, 2014). This rule was codified at 12 CFR part 1081, subpart E. Collectively, the rules codified at 12 CFR part 1081 are titled “Rules of Practice for Adjudication Proceedings” (Rules).

The Rules pertain to the general conduct of administrative adjudication proceedings, the initiation of such proceedings and prehearing rules, hearings, decisions and appeals, and temporary cease-and-desist proceedings. To date, there have been eight administrative adjudication proceedings under the Rules that were not immediately resolved by the issuance of a consent order pursuant to 12 CFR 1081.200(d). Six of these proceedings were settled during the course of the adjudication, one proceeding is pending, and one proceeding has resulted in a final decision.

The Bureau is, as described below, issuing this request for information seeking public comment on whether and how it might improve its administrative adjudication processes, including the Rules, while continuing to achieve the Bureau's statutory purposes and objectives.

#### Overview of This Request for Information

The Bureau is using this request for information to seek public input regarding the Rules. The Bureau encourages comments from all interested members of the public. The Bureau anticipates that the responding public may include entities that have participated in Bureau administrative adjudication proceedings or similar proceedings at other agencies, members of the bar who represent these entities, agencies that utilize an administrative adjudication process, individual consumers, consumer advocates, regulators, and researchers or members of academia.

Section 1053 of the Act authorizes the Bureau to conduct administrative adjudications. The Bureau in the past has brought cases in the administrative setting in accordance with applicable law. The Bureau understands, however, that the administrative adjudication process can result in undue burdens, impacts, or costs on the parties subject to these proceedings. Members of the public are likely to have useful information and perspectives on the benefits and impacts of the Bureau's use of administrative adjudications, as well as existing administrative adjudication processes and the Rules. The Bureau is especially interested in receiving suggestions for whether it should be availing itself of the administrative

adjudication process, and if so how its processes and Rules could be updated, streamlined, or revised to better achieve the Bureau's statutory objectives; to minimize burdens, impacts, or costs on parties subject to these proceedings; to align the Bureau's administrative adjudication Rules more closely with those of other agencies; and to better provide fair and efficient process to individuals and entities involved in the adjudication process, including ensuring that they have a full and fair opportunity to present evidence and arguments relevant to the proceeding. Interested parties may also be well-positioned to identify those parts of the Bureau's administrative adjudication processes and Rules that they believe may be most in need of improvement, and, thus, assist the Bureau in prioritizing and properly tailoring its process for reviewing its processes and Rules. In short, engaging members of the public in an open, transparent process will help inform the Bureau's review of its processes related to administrative adjudications.

#### Questions for Commenters

To allow the Bureau to more effectively evaluate suggestions, the Bureau requests that, where possible, comments include:

- Specific discussion of the positive and negative aspects of the Bureau's administrative adjudication processes, including whether a policy of proceeding in Federal court in all instances would be preferable;
- Specific suggestions regarding any potential updates or modifications to the Bureau's administrative adjudication processes, including the Bureau's Rules, consistent with the Bureau's statutory purposes and objectives, and including, in as much detail as possible, the potential update or modification, supporting data or other information on impacts and costs, or information concerning alignment with the processes of other agencies; and
- Specific identification of any aspects of the Bureau's administrative adjudication processes, including the Bureau's Rules, that should not be modified, consistent with the Bureau's statutory purposes and objectives, and including, in as much detail as possible, supporting data or other information on impacts and costs, information related to consumer and public benefit resulting from these processes, or information concerning alignment with the processes of other agencies.

The following list of general areas represents a preliminary attempt by the Bureau to identify elements of Bureau

processes related to administrative adjudications that may be deserving of more immediate focus. This non-exhaustive list is meant to assist in the formulation of comments and is not intended to restrict the issues that may be addressed. In addressing these questions or others, the Bureau requests that commenters identify with specificity the Bureau regulations or practices at issue, providing legal citations where appropriate and available. Please feel free to comment on some or all of the questions below, but please be sure to indicate on which area you are commenting.

The Bureau is seeking feedback on all aspects of its administrative adjudication process, including but not limited to:

1. Whether, as a matter of policy, the Bureau should pursue contested matters only in Federal court rather than through the administrative adjudication process;
2. The Rules' protection of the rights and interests of third parties;
3. 12 CFR 1081.200(b)'s requirements for the contents of the Bureau's notice of charges;
4. The policy, expressed in 12 CFR 1081.101 for administrative adjudication proceedings to be conducted expeditiously, including:
  - a. 12 CFR 1081.201(a)'s requirement that respondents file an answer to a notice of charges within 14 days;
  - b. 12 CFR 1081.115(b)'s requirement that the hearing officer in administrative adjudications strongly disfavor motions for extensions of time except upon a showing of substantial prejudice;
  - c. 12 CFR 1081.212(h)'s requirement that the hearing officer decide any motion for summary disposition within 30 days; and
  - d. the Bureau's implementation of the requirement in 12 U.S.C. 5563(b)(1)(B) that hearings take place within 30 to 60 days of the notice of charges, unless the respondent seeks an extension of that time period;
5. 12 CFR 1081.206's requirements that the Bureau make documents available for copying or inspection, including whether the Bureau should produce those documents in electronic form to respondents in the first instance, at the Bureau's expense;
6. 12 CFR 1081.208's requirements for issuing subpoenas, and whether counsel for a party should be entitled to issue subpoenas without leave of the hearing officer;
7. 12 CFR 1081.209(g)(3)'s provision that failure to object to a question or document at a deposition is, with some exception, not deemed a waiver of the objection;

8. 12 CFR 1081.210(b)'s limitation on the number of expert witnesses any party may call at a hearing, absent "extraordinary circumstances";

9. 12 CFR 1081.210(c)'s requirements for expert reports, including whether that paragraph should expressly incorporate the requirements of the Federal Rules of Civil Procedure relating to the required disclosures of expert witnesses;

10. 12 CFR 1081.212(e)'s instruction that extensions of the length limitation for motions for summary disposition are disfavored;

11. 12 CFR 1081.303(b)'s rules pertaining to admissible evidence in administrative adjudications, including:

- a. Whether, in general, the Bureau should expressly adopt the Federal Rules of Evidence; and
- b. whether, if the Bureau does not expressly adopt the Federal Rules of Evidence, the acceptance of prior testimony hearsay evidence pursuant to 12 CFR 1081.303(b)(3) should comply with the requirements of Federal Rule of Evidence 804(b)(1);

12. The Rules' lack of authorization for parties to conduct certain discovery, including deposing fact witnesses or serving interrogatories; and

13. Whether respondents should be afforded the opportunity to stay a decision of the Director pending appeal by filing a supersedeas bond, consistent with Federal Rule of Civil Procedure 62(d).

**Authority:** 12 U.S.C. 5511(c).

Dated: January 30, 2018.

**Mick Mulvaney,**

*Acting Director, Bureau of Consumer Financial Protection.*

[FR Doc. 2018-02208 Filed 2-2-18; 8:45 am]

**BILLING CODE 4810-AM-P**

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Parts 1500 and 1507

[Docket No. CPSC-2006-0034]

#### Amendments to Fireworks Regulations; Notice of Opportunity for Oral Presentation of Comments

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking; opportunity for oral presentation of comments.

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**SUMMARY:** The Consumer Product Safety Commission (Commission or CPSC) will be holding a meeting to provide interested parties with an opportunity to present oral comments on the notice of

proposed rulemaking (NPR) the Commission issued regarding amendments to the fireworks regulations. Any oral comments will be part of the rulemaking record.

**DATES:** The meeting will begin at 10 a.m. Eastern Standard Time (EST) on March 7, 2018. The Office of the Secretary must receive requests to make oral presentations, along with the written text of the oral presentations, no later than 5 p.m. EST on February 28, 2018.

**ADDRESSES:** The meeting will be in the Hearing Room, on the 4th Floor of the Bethesda Towers Building, 4330 East-West Highway, Bethesda, MD 20814. Submit requests to make oral presentations and the written text of oral presentations to the Office of the Secretary, with the caption, "Fireworks NPR; Oral Presentation," by email to [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov), or by mail to the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814.

**FOR FURTHER INFORMATION CONTACT:** For information about the subject matter of this meeting, contact Rodney Valliere, Project Manager, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2526. For information about the procedure to make an oral presentation, contact Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504-7923.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On February 2, 2017, the Commission published an NPR in the **Federal Register**, proposing to amend its fireworks regulations under the Federal Hazardous Substances Act (FHSA; 15 U.S.C. 1261-1278), and seeking written comments. 82 FR 9012. The NPR proposed amendments that would create new requirements for fireworks devices, as well as modify or clarify existing requirements. On April 14, 2017, the Commission published a notice extending the comment period for the NPR to July 17, 2017. 82 FR 17947. The NPR is available at: <https://www.gpo.gov/fdsys/pkg/FR-2017-02-02/pdf/2017-02014.pdf> and Commission staff's briefing package for the NPR is available at: <https://www.cpsc.gov/s3fs-public/ProposedRuleAmendmentsToFireworksRegulations.pdf>.

In the Request for Comments section of the NPR (82 FR 9029), the

Commission sought information on specific topics, in addition to requesting comments on all aspects of the proposed rule. Comments on the topics listed in the NPR would be helpful at the public hearing. In particular, the Commission would find information and data on the following topics useful:

- The public safety need for the proposed chemical composition and pyrotechnic weight limits for ground devices;
- the public safety need for prohibiting hexachlorobenzene and lead tetroxide and other lead compounds in fireworks devices;
- the public safety need for the proposed test method to evaluate side ignition and the appropriateness of the proposed ignition-resistance period;
- the public safety need for the proposed ban of fireworks devices that project fragments when functioning; and
- the appropriate trace contamination allowance levels for prohibited chemicals.

##### II. The Public Meeting

Under the FHSA and the Administrative Procedure Act (5 U.S.C. 551-562), the Commission must provide interested parties with an opportunity to submit "written data, views, or arguments" regarding a proposed rule. 5 U.S.C. 553(c). Neither statute requires the Commission to provide an opportunity for oral comments about a rulemaking, but the Commission is providing this forum to give interested parties an additional opportunity to comment on the NPR.

To request the opportunity to make an oral presentation, see the information under the **DATES** and **ADDRESSES** sections of this notice. Participants should limit their presentations to approximately 10 minutes, excluding time for questioning by the Commissioners or CPSC staff. To avoid duplicate presentations, groups should designate a spokesperson, and the Commission reserves the right to limit presentation times or impose further restrictions, as necessary.

**Alberta E. Mills,**

*Acting Secretary, Consumer Product Safety Commission.*

[FR Doc. 2018-02258 Filed 2-2-18; 8:45 am]

**BILLING CODE 6355-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 2 and 25

[IB Docket No. 16-408; Report No. 3084]

#### Petitions for Reconsideration of Action in Rulemaking Proceeding

**AGENCY:** Federal Communications Commission.

**ACTION:** Petitions for reconsideration.

**SUMMARY:** Petitions for Reconsideration (Petitions) have been filed in the Commission's rulemaking proceeding by Joseph A. Godles, on behalf of Iridium Constellation LLC et al., Brian D. Weimer, on behalf of WorldVu Satellites Limited, and John P. Janka, on behalf of Viasat, Inc.

**DATES:** Oppositions to the Petitions must be filed on or before February 20, 2018. Replies to an opposition must be filed on or before March 2, 2018.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Clay DeCell, 202-418-0803, [Clay.DeCell@fcc.gov](mailto:Clay.DeCell@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's document, Report No. 3084, released January 26, 2018. The full text of the Petitions is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW, Room CY-A257, Washington, DC 20554. They also may be accessed online via the Commission's Electronic Comment Filing System at: <http://apps.fcc.gov/ecfs/>. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. because no rules are being adopted by the Commission.

*Subject:* Update to Parts 2 and 25 Concerning Non-Geostationary, Fixed-Satellite Service Systems and Related Matters, FCC 17-122, published at 82 FR 59972, December 18, 2017. This document is being published pursuant to 47 CFR 1.429(e). See also 47 CFR 1.4(b)(1) and 1.429(f), (g).

*Number of Petitions Filed:* 3.

Federal Communications Commission.

**Marlene H. Dortch,**

*Office of the Secretary, Office of Managing Director.*

[FR Doc. 2018-02195 Filed 2-2-18; 8:45 am]

**BILLING CODE 6712-01-P**

# Notices

Federal Register

Vol. 83, No. 24

Monday, February 5, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Indiana Advisory Committee to the U.S. Commission on Civil Rights

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting on Saturday February 17, 2018, from 11:30 a.m.–1:00 p.m. CST for the purpose of hearing public testimony on voting rights issues in the state.

**DATES:** The meeting will be held on Saturday, February 17, 2018, from 11:30 a.m.–1:00 p.m. CST

**LOCATION:** The community forum will take place at the Evansville Central Library, Browning Rooms A&B, 200 SE, Martin Luther King Jr. Blvd., Evansville, Indiana 47713.

**PUBLIC CALL INFORMATION:** Dial: 877–329–7568; Conference ID 3466041.

**FOR FURTHER INFORMATION CONTACT:** Melissa Wojnaroski, DFO, at [mwojnaroski@usccr.gov](mailto:mwojnaroski@usccr.gov) or 312–353–8311.

**SUPPLEMENTARY INFORMATION:** This meeting is free and open to the public. Members of the public may appear in person and participate. This meeting is also available to the public through the above listed toll free call in number (audio only). Members of the public will be invited to make a statement as time allows.

For those individuals who join by phone, the conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular

charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at [callen@usccr.gov](mailto:callen@usccr.gov). Persons who desire additional information may contact the Regional Programs Unit Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via [www.facadatabase.gov](http://www.facadatabase.gov) under the Commission on Civil Rights, Indiana Advisory Committee link (<http://www.facadatabase.gov/committee/meetings.aspx?cid=247>). Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit Office at the above email or street address.

This is the second in a series of public meetings the Committee will hold on this topic. The Committee will also meet on Monday February 12, 2018 via web conference, and in Indianapolis on Friday March 2, 2018 to hear additional testimony. Please consult the **Federal Register** or contact the Regional Programs Unit for additional information on these meetings.

### Agenda

Welcome and Introductions  
Public Comment: Voting Rights in Indiana  
Closing Statements  
Adjournment

Dated: January 31, 2018.

**David Mussatt,**  
*Supervisory Chief, Regional Programs Unit.*  
[FR Doc. 2018–02185 Filed 2–2–18; 8:45 am]

**BILLING CODE P**

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Indiana Advisory Committee to the U.S. Commission on Civil Rights

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting via web conference on Monday February 12, 2018, from 3:00 p.m.–4:30 p.m. EST for the purpose of hearing public testimony on voting rights issues in the state.

**DATES:** The meeting will be held on Monday, February 12, 2018, at 3:00 p.m. EST.

**Public Call Information:** (audio only)  
Dial: 877–419–6590, Conference ID: 9439336.

**Web Access Information:** (visual only)  
The online portion of the meeting may be accessed through the following link: <https://cc.readytalk.com/r/b42f10vd2g3e&eom>.

**FOR FURTHER INFORMATION CONTACT:** Melissa Wojnaroski, DFO, at [mwojnaroski@usccr.gov](mailto:mwojnaroski@usccr.gov) or 312–353–8311.

**SUPPLEMENTARY INFORMATION:** Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll free number (audio only) and web access link (visual only). Please use both the call in number and the web access link in order to follow the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines,

according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 55 W Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353-8324, or emailed to Carolyn Allen at [callen@usccr.gov](mailto:callen@usccr.gov). Persons who desire additional information may contact the Regional Programs Unit Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via [www.facadatabase.gov](http://www.facadatabase.gov) under the Commission on Civil Rights, Indiana Advisory Committee link (<http://www.facadatabase.gov/committee/meetings.aspx?cid=247>).

Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit Office at the above email or street address.

This is the first in a series of public meetings the Committee will hold on this topic. The Committee will also meet in Evansville, Indiana on Saturday February 17th, 2018; and in Indianapolis on Friday March 2, 2018 to hear additional testimony. Please consult the **Federal Register** or contact the Regional Programs Unit for additional information on these meetings.

**Agenda**

- Welcome and Roll Call
- Panel Presentations: Voting Rights in Indiana
- Public Comment
- Future Plans and Actions
- Adjournment

**EXCEPTIONAL CIRCUMSTANCE:** Pursuant to 41 CFR 102-3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of this Committee doing work on the FY 2018 statutory enforcement report.

Dated: January 31, 2018.

**David Mussatt,**  
*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2018-02184 Filed 2-2-18; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF COMMERCE**

**Economic Development Administration**

**Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance**

**AGENCY:** Economic Development Administration, U.S. Department of Commerce.

**ACTION:** Notice and opportunity for public comment.

**SUMMARY:** The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

**SUPPLEMENTARY INFORMATION:**

**LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE**  
[01/16/2018 through 01/30/2018]

| Firm name                    | Firm address                               | Date accepted for investigation | Product(s)   |
|------------------------------|--|---------------------------------|--|
| Sawbrook Steel Casting, LLC  | 425 Shepherd Avenue, Cincinnati, OH 45215. | 01/18/2018                      | The firm manufactures alloy steel castings, such as bearing bases.   |
| Liberty Casting Company, LLC | 620 Liberty Road, Delaware, OH 43015.      | 01/30/2018                      | The firm manufactures gray, ductile, and high-alloy iron castings, such as blower housings and rotor hubs. |
| Maloya Laser, Inc. ....      | 65A Mall Drive, Commack, NY 11725.         | 01/30/2018                      | The firm manufactures custom fabricated metal components and systems.                                      |

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR

315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

**Irette Patterson,**

*Program Analyst.*

[FR Doc. 2018-02260 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-WH-P**

**DEPARTMENT OF COMMERCE**

**Bureau of Industry and Security**

**Proposed Information Collection; Comment Request; Request for the Appointment of a Technical Advisory Committee**

**AGENCY:** Bureau of Industry and Security.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and

respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before April 6, 2018.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at [PRAcomments@doc.gov](mailto:PRAcomments@doc.gov)).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to Mark Crace, BIS ICB Liaison, (202) 482-8093 or at [mark.crace@bis.doc.gov](mailto:mark.crace@bis.doc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

This collection of information is required by the Export Administration Regulations and the Federal Advisory Committee Act. The Technical Advisory Committees (TACs) were established to advise and assist the U.S. Government on export control matters such as proposed revisions to export control lists, licensing procedures, assessments of the foreign availability of controlled products, and export control regulations. Under this collection, interested parties may submit a request to BIS to establish a new TAC. The Bureau of Industry and Security provides administrative support for these committees.

**II. Method of Collection**

Submitted electronically or in paper form.

**III. Data**

*OMB Control Number:* 0694-0199.

*Form Number(s):* None.

*Type of Review:* Regular submission.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents:* 1.

*Estimated Time per Response:* 5 hours.

*Estimated Total Annual Burden Hours:* 5.

*Estimated Total Annual Cost to Public:* \$0.

**IV. Request for Comments**

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

**Sheleen Dumas,**

*Departmental Lead PRA Officer, Office of the Chief Information Officer.*

[FR Doc. 2018-02182 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-33-P**

**DEPARTMENT OF COMMERCE**

**International Trade Administration**

[C-570-923]

**Raw Flexible Magnets From the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2016**

**AGENCY:** Enforcement and Compliance, International Trade Administrative, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty order on raw flexible magnets from the People's Republic of China (China) covering the period January 1, 2016, through December 31, 2016.

**DATES:** Effective February 5, 2018.

**FOR FURTHER INFORMATION CONTACT:** Patricia Tran, AD/CVD Operations, Office III, Enforcement & Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1503.

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 13, 2017, based on a timely request by Qwik Picz Photo Booth, LLC (Qwik Picz), Commerce published in the **Federal Register** a notice of initiation of an administrative review of the countervailing duty order on raw flexible magnets from China with respect to two companies, SOM International Limited and Wenzhou

Haibao Printing Co., LTD.<sup>1</sup> On January 16, 2018, pursuant to 19 CFR 351.213(d)(1), Qwik Picz timely withdrew its request for an administrative review of both companies.<sup>2</sup>

**Rescission of Administrative Review**

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. Qwik Picz withdrew its review request by the 90-day deadline, and no other parties requested an administrative review of this order. Therefore, we are rescinding the administrative review of the countervailing duty order on raw flexible magnets from China covering the period January 1, 2016, to December 31, 2016, in its entirety.

**Assessment**

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Because Commerce is rescinding this administrative review in its entirety, the entries to which this administrative review pertains shall be assessed countervailing duties that are equal to the cash deposits of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP within 15 days after the publication of this notice in the **Federal Register**.

**Administrative Protective Orders**

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the

<sup>1</sup> See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 82 FR 52268 (November 13, 2017).

<sup>2</sup> See Letter from Qwik Picz, regarding, "Raw Flexible Magnets from the PRC; C-570-923; Withdraw Request for Review by Qwik Picz Photo Booth, LLC," dated January 16, 2018.

regulations and terms of an APO is a violation which is subject to sanction.

#### Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: January 30, 2018.

**James Maeder,**

*Senior Director performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2018-02210 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* Socioeconomics of Guided Whale-Watching Operations in the Stellwagen Bank National Marine Sanctuary.

*OMB Control Number:* 0648-xxxx.

*Form Number(s):* None.

*Type of Request:* Regular (request for a new information collection).

*Number of Respondents:* 30.

*Average Hours per Response:* One hour and 45 minutes.

*Burden Hours:* 53.

*Needs and Uses:* This request is for a new information collection to benefit natural resource managers in Stellwagen Bank National Marine Sanctuary (SBNMS).

The National Ocean Service (NOS) proposes to collect information from wildlife watching operations to ascertain the market value of marine wildlife via the ocean recreational industry in the Stellwagen Bank/Gulf of Maine region.

Up-to-date socioeconomic data is needed to support the conservation and management goals of SBNMS to strengthen and improve conservation of marine wildlife, including whales, pinnipeds, seals, and seabirds within the jurisdiction of the sanctuary and to satisfy legal mandates.

SBNMS is currently in the process of updating the 2010 Management Plan, and has identified a lack of baseline

socioeconomic information on ocean recreation businesses. The type of data targeted for this collection has not been updated since 2008 and there are no source so information that detail operators' perceptions and attitudes towards the industry and sanctuary. Thus, current information on the importance of marine wildlife to the local tourism industry and operators is required. The primary focus for the survey will be to gather data on the non-consumptive, person-days of marine wildlife viewing and operators' perceptions and attitudes. Specifically, researchers will collect data to help determine the contribution of marine wildlife watching operations to the economy in the Stellwagen Bank region. The number of person-days of wildlife viewing is necessary to estimate the economic value that the industry makes to the region.

*Affected Public:* Business or other for-profit organizations.

*Frequency:* Once.

*Respondent's Obligation:* Voluntary.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA\_Submission@omb.eop.gov* or fax to (202) 395-5806.

Dated: January 30, 2018.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2018-02166 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-NK-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XF967**

#### Atlantic Highly Migratory Species; Atlantic Shark Management Measures; 2018 Research Fishery

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of public meeting.

**SUMMARY:** On November 3, 2017, NMFS published a notice inviting qualified commercial shark permit holders to submit applications to participate in the 2018 shark research fishery. The shark research fishery allows for the collection of fishery-dependent data for future

stock assessments and cooperative research with commercial fishermen to meet the shark research objectives of the Agency. Every year, the permit terms and permitted activities (e.g., number of hooks and retention limits) specifically authorized for selected participants in the shark research fishery are designated depending on the scientific and research needs of the Agency, as well as the number of NMFS-approved observers available. In order to inform selected participants of this year's specific permit requirements and ensure all terms and conditions of the permit are met, NMFS is holding a mandatory permit holder meeting (via conference call) for selected participants. The date and time of that meeting is announced in this notice.

**DATES:** A conference call will be held on February 16, 2018.

**ADDRESSES:** A conference call will be conducted. See **SUPPLEMENTARY INFORMATION** for information on how to access the conference call.

**FOR FURTHER INFORMATION CONTACT:** Karyl Brewster-Geisz or Guy DuBeck at (301) 427-8503 or Delisse Ortiz at (240) 681-9037.

**SUPPLEMENTARY INFORMATION:** The Atlantic shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The 2006 Consolidated Highly Migratory species (HMS) Fishery Management Plan (FMP) is implemented by regulations at 50 CFR part 635.

The final rule for Amendment 2 to the 2006 Consolidated HMS FMP (73 FR 35778, June 24, 2008, corrected at 73 FR 40658, July 15, 2008) established, among other things, a shark research fishery to maintain time-series data for stock assessments and to meet NMFS' research objectives. The shark research fishery gathers important scientific data and allows selected commercial fishermen the opportunity to earn more revenue from selling the sharks caught, including sandbar sharks. Only the commercial shark fishermen selected to participate in the shark research fishery are authorized to land/harvest sandbar sharks subject to the sandbar quota available each year. The 2018 sandbar shark quota is 90.7 mt dw per year. The selected shark research fishery participants also have access to the research large coastal shark, small coastal shark, and pelagic shark quotas subject to retention limits and quotas per §§ 635.24 and 635.27, respectively.

On November 3, 2017 (82 FR 51218), NMFS published a notice inviting qualified commercial shark directed and

incidental permit holders to submit an application to participate in the 2018 shark research fishery. NMFS received six applications, of which all six applicants were determined to meet all the qualifications. NMFS selected all six qualified participants after considering how to meet research objectives in particular regions. NMFS expects to invite qualified commercial shark permit holders to submit an application for the 2019 shark research fishery later in 2018.

As with past years, the 2018 permit terms and permitted activities (*e.g.*, number of hooks and retention limits) specifically authorized for selected participants in the shark research fishery were designated depending on the scientific and research needs of the Agency, as well as the number of NMFS-approved observers available. In order to inform selected participants of this year's specific permit requirements and ensure all terms and conditions of the permit are met, per the requirements of § 635.32 (f)(4), NMFS is holding a mandatory permit holder meeting via conference call.

#### Conference Call Date, Time, and Dial-in Number

The conference call will be held on February 16, 2018, from 1:30 to 3:30 p.m. (EST). Participants and interested parties should call 1-888-942-9261 and use the passcode 8567825. Selected participants who do not attend will not be allowed to participate in the shark research fishery. While the conference call is mandatory for selected participants, other interested parties may call in and listen to the discussion.

Selected participants are encouraged to invite their captain, crew, or anyone else who may assist them in meeting the terms and conditions of the shark research fishery permit.

Dated: January 31, 2018.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2018-02236 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the

Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* West Coast Groundfish Trawl Economic Data Collection.

*OMB Control Number:* 0648-0618.

*Form Number(s):* None.

*Type of Request:* Regular (extension of a currently approved information collection).

*Number of Respondents:* 206.

*Average Hours per Response:* Catcher vessels, catcher-processors and motherships, 8 hours each; shore-based processors, 20 hours.

*Burden Hours:* 2,224.

*Needs and Uses:* This information collection is needed in order to meet the monitoring requirements of the Magnuson-Stevens Act (MSA). In particular, the Northwest Fisheries Science Center (NWFSC) needs economic data on all harvesters, first receivers, shorebased processors, catcher processors, and motherships participating in the West Coast groundfish trawl fishery.

The currently approved collection covers collection of data for the 2014-2016 operating years. The renewed approval will cover years 2017-2019. Data will be collected from all catcher vessels registered to a limited entry trawl endorsed permit, catcher processors registered to catcher processor permits, and motherships registered to mothership permits, first receivers, and shorebased processors that received round or head-and-gutted IFQ groundfish or whiting from a first receiver to provide the necessary information for analyzing the effects of the West Coast Groundfish Trawl Catch Share Program.

As stated in 50 CFR 660.114, the EDC forms due on September 1, 2018 will provide data for the 2017 operating year.

*Affected Public:* Business or other for-profit organizations.

*Frequency:* Annually.

*Respondent's Obligation:* Mandatory.

This information collection request may be viewed at [reginfo.gov](http://reginfo.gov). Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to (202) 395-5806.

Dated: January 30, 2018.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2018-02167 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Science Advisory Board

**AGENCY:** Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice of renewal of charter.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (FACA), and after consultation with the General Services Administration, the Chief Financial Officer and Assistant Secretary for Administration have determined that renewal of the NOAA Science Advisory Board is in the public interest. The committee has been a successful undertaking and has provided advice to the Under Secretary for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. The committee will continue to provide such advice and recommendations in the future.

The structure and responsibilities of the Committee are unchanged from when it was originally established in September 1997. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act.

**FOR FURTHER INFORMATION CONTACT:** Dr. Cynthia Decker, Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Phone Number: 301-734-1156. Email: [Cynthia.Decker@noaa.gov](mailto:Cynthia.Decker@noaa.gov); or visit the NOAA SAB website at <http://www.sab.noaa.gov>.

Dated: June 29, 2017.

**David Holst,**

*Chief Financial/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.*

**Editorial note:** This document was received for publication by the Office of the Federal Register on January 30, 2018.

[FR Doc. 2018-02099 Filed 2-2-18; 8:45 am]

**BILLING CODE 3510-KD-P**

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

XRIN 0648–XF547

**Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Haines Ferry Terminal Modification Project**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; Issuance of Incidental Harassment Authorization.

**SUMMARY:** In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the Alaska Department of Transportation and Public Facilities (ADOT&PF) to incidentally take, by Level A and/or Level B harassment, six species of marine mammals during the Haines Ferry Terminal Modification Project, Haines, Alaska.

**DATES:** The IHA is valid from October 1, 2018, through September 30, 2019.

**FOR FURTHER INFORMATION CONTACT:** Jaclyn Daly, Office of Protected Resources, NMFS, (301) 427–8401.

**Availability**

An electronic copy of the IHA and supporting documents, as well as a list of the references cited in this document, may be obtained online at: [www.nmfs.noaa.gov/pr/permits/incidental/construction.htm](http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm). In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

**SUPPLEMENTARY INFORMATION:****Background**

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will

not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined “negligible impact” in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

NMFS has defined “unmitigable adverse impact” in 50 CFR 216.103 as an impact resulting from the specified activity:

(1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and

(2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The MMPA states that the term “take” means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

**National Environmental Policy Act**

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our action with respect to environmental consequences on the human environment. The issuance of the IHA is consistent with categories of activities identified in categorical exclusion (CE) B4 of the Companion Manual for NOAA Administrative Order 216–6A. These activities do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we

have not identified any extraordinary circumstances that would preclude use of this categorical exclusion.

**Summary of Request**

On January 9, 2017, NMFS received a request from ADOT&PF for an IHA to take marine mammals incidental to the Haines Ferry Terminal Modification Project. ADOT&PF submitted a subsequent application on May 30, 2017, which we considered adequate and complete. On August 17, 2017, ADOT&PF indicated a change to the requested effective dates in the application to accommodate a delayed construction schedule. ADOT&PF’s request is for harassment only and NMFS concurs that serious injury or mortality is not expected to result from this activity. Therefore, an IHA is appropriate.

NMFS has issued an IHA to ADOT&PF authorizing the take of humpback whales (*Megaptera novaeangliae*), harbor seals (*Phoca vitulina*), harbor porpoise (*Phocoena phocoena*), and Dall’s porpoise (*Phocoenoides dalli*) by Level A and Level B harassment, and an additional two species, Steller sea lion (*Eumetopias jubatus*) and killer whale (*Orcinus orca*) by Level B harassment only. Pile driving will occur for 19 days and pile removal will take 2 additional days (total of 21 days) over the course of 4 months from October 1, 2018, through September 30, 2019, but excluding March 1 through May 31, 2019. No subsequent IHA would be necessary to complete the project.

**Description of Proposed Activity**

We provided a description of the specified activity in our **Federal Register** notice announcing the proposed authorization (82 FR 47700; October 13, 2017). Please refer to that document; we provide only summary information here.

The Haines Ferry Terminal Modification Project involves constructing an AMHS End Berth Facility adjacent to the existing dock. The expansion is necessary because the current configuration does not allow for operation of the new Alaska Class vessels, which are expected to be operational in 2018. Activities which have the potential to harass marine mammals include include impact and vibratory pile driving and vibratory pile removal. The terminal is located in southeast Alaska in Lutak Inlet.

To construct the new infrastructure, ADOT&PF will install 37 new piles (22 30-in. piles and 15 36-in. piles). Each pile will require 45 to 60 minutes of vibratory driving (to account for proper

placement and alignment of the pile) followed by an average of 700 strikes (15 to 30 minutes) of the impact hammer for a total average installation time of 60–90 minutes. Pile driving the 30-in. piles is expected to take 11 days while an additional 8 days would be necessary to install the 36-in. piles. In addition, 4 existing 30-in. piles would be removed over the course of 2 days. In total, ADOT&PF would be elevating noise levels around the project area for 21 days (two days of pile removal plus 19 days of pile driving) of a 4 month construction window (four months from October 1, 2018, through September 30, 2019, excluding March 1, 2019, through May, 31 2019).

**Comments and Responses**

A notice of NMFS’s proposal to issue an IHA to ADOT&PF was published in the **Federal Register** on October 13, 2017 (82 FR 47700). That notice described, in detail, ADOT&PF’s

activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, proposed amount and manner of take, and proposed mitigation, monitoring and reporting measures. During the 30-day public comment period, NMFS received one comment letter from the Marine Mammal Commission (Commission); the Commission’s recommendations and our responses are provided here, and the comments have been posted online at: [www.nmfs.noaa.gov/pr/permits/incidental/construction.htm](http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm).

*Comment 1:* The Commission recommends that NMFS share the rounding criteria with the Commission in the near term.

*Response:* NMFS will share the rounding criteria with the Commission soon (following the completion of internal edits) and looks forward to discussing the issue with them in the future.

**Description of Marine Mammals in the Area of Specified Activities**

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS Stock Assessment Reports (SAR; [www.nmfs.noaa.gov/pr/sars/](http://www.nmfs.noaa.gov/pr/sars/)), and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS website ([www.nmfs.noaa.gov/pr/species/mammals/](http://www.nmfs.noaa.gov/pr/species/mammals/)). We provided a description of the specified activity in our **Federal Register** notice announcing the proposed authorization (82 FR 47700; October 13, 2017). Please refer to that document; we provide only a summary table here (Table 1).

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT WITHIN UPPER LYNN CANAL DURING THE SPECIFIED ACTIVITY

| Common name  | Scientific name                    | MMPA stock                                    | ESA/MMPA status; strategic (Y/N) <sup>1</sup> | Stock abundance Nbest, (CV, N <sub>min</sub> , most recent abundance survey) <sup>2</sup> | PBR   | Annual M/SI <sup>3</sup> |
|--|------------------------------------|---|---|---|-------|--------------------------|
| <b>Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)</b> |                                    |   |   |   |       |                          |
| <b>Family Balaenidae</b>   |                                    |   |   |   |       |                          |
| Humpback whale .....   | <i>Megaptera novaeangliae</i>      | Central North Pacific .....                   | E, D, Y                                       | 10,103 (0.3, 7,890, 2006).  | 83    | 24                       |
| <b>Superfamily Odontoceti (toothed whales, dolphins, and porpoises)</b>    |                                    |   |   |   |       |                          |
| <b>Family Delphinidae</b>  |                                    |   |   |   |       |                          |
| Killer whale .....   | <i>Orcinus orca</i> .....          | Alaska Resident .....                         | -, N  | 2,347 (N/A, 2,347, 2012) <sup>4</sup> .   | 24    | 1                        |
|  |                                    | Northern Resident .....                       | -, N  | 261 (N/A, 261, 2011) <sup>4</sup> ..  | 1.96  | 0                        |
|  |                                    | Gulf of Alaska, Aleutian Islands, Bering Sea. | -, N  | 587 (N/A, 587, 2012) <sup>4</sup> ..  | 5.9   | 1                        |
|  |                                    | West Coast Transient ...                      | -, N  | 243 (N/A, 243, 2009) <sup>4</sup> ..  | 2.4   | 0                        |
| <b>Family Phocoenidae (porpoises)</b>                                      |                                    |   |   |   |       |                          |
| Harbor porpoise .....  | <i>Phocoena phocoena</i> .....     | Southeast Alaska .....                        | -, Y  | 975 (0.10, 896, 2012) <sup>5</sup>  | 8.9   | <sup>5</sup> 34          |
| Dall’s porpoise .....  | <i>Phocoenoides dalli</i> .....    | Alaska .....                                  | -, N  | 83,400 (0.097, N/A, 1993).  | Undet | 38                       |
| <b>Order Carnivora—Superfamily Pinnipedia</b>                              |                                    |   |   |   |       |                          |
| <b>Family Otariidae (eared seals and sea lions)</b>                        |                                    |   |   |   |       |                          |
| Steller sea lion .....   | <i>Eumetopias jubatus</i> .....    | Western U.S. ....                             | E, D, Y                                       | 49,497 (2014) .....   | 297   | 233                      |
|  |                                    | Eastern U.S. ....                             | -, D, Y                                       | 60,131–74,448 (2013) ..   | 1,645 | 92.3                     |
| <b>Family Phocidae (earless seals)</b>                                     |                                    |   |   |   |       |                          |
| Harbor seal .....  | <i>Phoca vitulina richardii</i> .. | Lynn Canal/Stephens Passage.                  | -, N  | 9,478 (8,605, 2011) .....   | 155   | 50                       |

<sup>1</sup> Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

<sup>2</sup> NMFS marine mammal stock assessment reports online at: [www.nmfs.noaa.gov/pr/sars/](http://www.nmfs.noaa.gov/pr/sars/). CV is coefficient of variation; N<sub>min</sub> is the minimum estimate of stock abundance. In some cases, CV is not applicable (N/A).

<sup>3</sup> These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

<sup>4</sup> N is based on counts of individual animals identified from photo-identification catalogs.

<sup>5</sup> In the 2016 SAR for harbor porpoise, NMFS identified population estimates and PBR for porpoises within inland southeast Alaska waters (these abundance estimates have not been corrected for g(0); therefore, they are likely conservative). The Annual M/SI value provided is for all Alaska fisheries, not just inland waters of southeast Alaska.

### Potential Effects of Specified Activities on Marine Mammals and Their Habitat

We provided a description of the anticipated effects of the specified activity on marine mammals in our **Federal Register** notice announcing the proposed authorization (82 FR 47700; October 13, 2017). Please refer to that document for our detailed analysis; we provide only summary information here.

The introduction of anthropogenic noise into the aquatic environment from pile driving and removal is the primary means by which marine mammals may be harassed from ADOT&PF's specified activity. The effects of pile driving noise on marine mammals are dependent on several factors, including, but not limited to, sound type (e.g., impulsive vs. non-impulsive), the species, age and sex class (e.g., adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Southall *et al.*, 2007, Wartzok *et al.*, 2004). Animals exposed to natural or anthropogenic sound may experience physical and behavioral effects, ranging in magnitude from none to severe (Southall *et al.*, 2007). In general, exposure to pile driving noise has the potential to result in auditory threshold shifts (permanent threshold shift (PTS) and temporary threshold shift (TTS)) and behavioral reactions (e.g., avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior).

In 2016, ADOT&PF documented observations of marine mammals during pile driving and down-hole drilling at the Kodiak Ferry Dock (as described in 80 FR 60636; October 7, 2015 [date]). In the marine mammal monitoring report for that project (ABR 2016), 1,281 Steller sea lions were observed within the Level B disturbance zone during pile driving or drilling (*i.e.*, documented as Level B take). Of these, 19 individuals demonstrated an alert behavior, 7 were fleeing, and 19 swam away from the project site. All other animals (98 percent) were engaged in activities such as milling, foraging, or fighting and did not change their behavior. In addition, two sea lions approached within 20 meters of active vibratory pile driving activities. Three harbor seals were observed within the disturbance zone

during pile-driving activities; none of them displayed disturbance behaviors. Fifteen killer whales and three harbor porpoise were also observed within the Level B harassment zone during pile driving. The killer whales were travelling or milling while all harbor porpoises were travelling. No signs of disturbance were noted for either of these species. Given the similarities in activities and habitat and the fact the same species are involved, we expect similar behavioral responses of marine mammals to the specified activity. That is, disturbance, if any, is likely to be temporary and localized (e.g., small area movements).

#### Marine Mammal Habitat Effects

We provided a description of the effect of specified activity on marine mammal habitat in our **Federal Register** notice announcing the proposed authorization (82 FR 47700; October 13, 2017). Please refer to that document; we provide only summary information here.

Construction activities at the Haines Ferry terminal could have localized, temporary impacts on marine mammal habitat and their prey by increasing in-water sound pressure levels and slightly decreasing water quality. ADOT&PF will employ standard construction best management practices (BMPs; see section 9 and 11.1 in ADOT's application), thereby, reducing any impacts. Any impacts are anticipated to be localized, short-term, and minimal.

#### Estimated Take

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

NMFS has authorized the taking of six species of marine mammals, by Level A and B harassment, incidental to pile driving and removal. Authorized takes

will primarily be by Level B harassment, as use of the impact and vibratory hammers has the potential to result in disruption of behavioral patterns and/or TTS for individual marine mammals. Impact pile driving may also result in auditory injury (Level A harassment) for mysticetes, high frequency cetaceans, and phocids based on modeled auditory injury zones if those species are exposed to certain noise levels generated from installing two piles per day. However, there are multiple hours between impact pile driving each pile; therefore, these zones are conservative as animals are not known to linger in the area. Therefore, PTS potential is low and, if occurs, would likely be minimal (e.g., PTS onset). Auditory injury is not expected for mid-frequency species and otariids as the accumulation of energy does not reach NMFS' PTS thresholds. The death of a marine mammal is also a type of incidental take. However, as described previously, no mortality is authorized for this activity. Below we describe how the take were calculated.

We estimated take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals may be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensounded above these levels in a day; (3) the density or occurrence of marine mammals within these ensounded areas; and, (4) and the number of days of activities.

#### Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 decibel (dB) re 1 microPascal ( $\mu$ Pa) root mean square (rms) for continuous (e.g. vibratory pile-driving, drilling) and above 160 dB re 1  $\mu$ Pa (rms) for non-explosive impulsive (e.g., seismic airguns, impact pile

driving) or intermittent (e.g., scientific sonar) sources. ADOT&PF includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving); therefore, the 120 and 160 dB re 1 μPa (rms) thresholds are applicable.

Level A harassment for non-explosive sources—NMFS’ Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Technical Guidance,

2016) identifies dual criteria to assess auditory injury (Level A harassment) for five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive).

These thresholds were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and

peer reviewers to inform the final product, and are provided in Table 2. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2016 Technical Guidance, which may be accessed at: <http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm>.

TABLE 2—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

| Hearing group                             | PTS onset acoustic thresholds* (received level)               |                                   |
|---|---|-----------------------------------|
|   | Impulsive   | Non-impulsive                     |
| Low-Frequency (LF) Cetaceans .....        | Cell 1: $L_{pk,flat}$ : 219 dB; $L_{E,LF,24h}$ : 183 dB ..... | Cell 2: $L_{E,LF,24h}$ : 199 dB.  |
| Mid-Frequency (MF) Cetaceans .....        | Cell 3: $L_{pk,flat}$ : 230 dB; $L_{E,MF,24h}$ : 185 dB ..... | Cell 4: $L_{E,MF,24h}$ : 198 dB.  |
| High-Frequency (HF) Cetaceans .....       | Cell 5: $L_{pk,flat}$ : 202 dB; $L_{E,HF,24h}$ : 155 dB ..... | Cell 6: $L_{E,HF,24h}$ : 173 dB.  |
| Phocid Pinnipeds (PW) (Underwater) .....  | Cell 7: $L_{pk,flat}$ : 218 dB; $L_{E,PW,24h}$ : 185 dB ..... | Cell 8: $L_{E,PW,24h}$ : 201 dB.  |
| Otariid Pinnipeds (OW) (Underwater) ..... | Cell 9: $L_{pk,flat}$ : 232 dB; $L_{E,OW,24h}$ : 203 dB ..... | Cell 10: $L_{E,OW,24h}$ : 219 dB. |

\* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

**Note:** Peak sound pressure ( $L_{pk}$ ) has a reference value of 1 μPa, and cumulative sound exposure level ( $L_E$ ) has a reference value of 1 μPa<sup>2</sup>s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript “flat” is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

*Ensonified Area*

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds.

ADOT&PF prepared an acoustic modeling report that discusses their modeling approach and identifies modeled source levels and harassment zones for the Haines Ferry Terminal project (Quijano *et al.*, 2016). A summary of the methods of the modeling effort is presented here; the full report is available at <http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm>.

To assess potential underwater noise exposure of marine mammals during pile driving, ADOT&PF used two models: a Pile Driving Source Model (PDSM) to estimate the sound radiation generated by the pile driver acting upon the pile (i.e., source levels), and a Full Waveform Range-dependent Acoustic Model (FWRAM) to simulate sound propagation away from the pile. The modeling considered the effect of pile driving equipment, bathymetry, sound speed profile, and seabed geoaoustic parameters to predict the acoustic footprint from impact and vibratory pile driving of cylindrical pipe piles with respect to NMFS Level A and Level B

thresholds. The report presents scenarios in which one pile or two piles are driven per day; however, for purposes here, NMFS considered only the two pile scenario since ADOT&PF has indicated that up to two piles could be driven per day. The resulting Level A harassment distances represent the location at which an animal would have to remain for the entire duration it takes to drive one pile, reset, and then drive another pile that, in reality, occurs over multiple hours in one day. The Level B isopleth distances represent instantaneous exposure to the Level B harassment criterion.

To model sounds resulting from impact and vibratory pile driving of 30-in and 36-in cylindrical pipe pipes, the PDSM was used in conjunction with GRL Engineer’s Wave Equation Analysis Program (GRLWEAP) pile driving simulation software to obtain an equivalent pile source signature (i.e., source level) consisting of a vertical array of discrete point sources (Table 3). This signature accounts for several parameters that describe the operation: Pile type, material, size, and length; the pile driving equipment; and approximate pile penetration rate. The amplitude and phase of the point sources along the array were computed so that they collectively mimicked the time-frequency characteristics of the

acoustic wave at the pile wall that results from a hammer strike (impact driving) or from forced vibration (vibratory driving) at the top end of the pile. This approach estimates spectral levels within the band 10–800 Hz where most of the energy from pile driving is concentrated. An extrapolation method (Zykov *et al.*, 2016) was used to extend modeled levels in 1/3-octave-bands up to 25 kHz, by applying a –2 dB per 1/3-octave-band roll-off coefficient to the SEL value starting at the 800 Hz band. This was done to estimate the acoustic energy at higher frequencies to compare to NMFS thresholds.

Once the pile source signature was computed, the FWRAM sound propagation modeling code was used to determine received levels as a function of depth, range, and azimuth direction. FWRAM is a time-domain acoustic model that used, as input, the PDSM-generated array of point sources representing the pile and computes synthetic pressure waveforms. To exclude sound field outliers, NMFS uses the maximum range at which the given sound level was encountered after excluding 5 percent of the farthest such points ( $R_{95\%}$ ) to estimate harassment threshold distances. To account for hearing groups, full-spectrum frequency-dependent weighting functions were applied at each

frequency. The model also showed the transition from down-slope to up-slope propagation as the sound crosses Lutak Inlet, resulting in a sound field that decays at a constant rate with range.

Steel cylindrical pipe piles 41 m (135 ft) long with 1/2 in thick walls were modeled for a total penetration of 14 m (46 ft) into the sediment. In the case of vibratory pile driving, both pile sizes were assumed to be driven by an ICE-44B vibratory pile driver. For impact

pile driving, the parameters corresponding to the Delmag D30-32 and D36-32 impact pile drivers were used to model scenarios with 30-in and 36-in diameter piles, respectively. Sound energy was accumulated over a specified number of hammer strikes, not as a function of time. The number of strikes required to install a single pile (assumed to be 700 strikes per pile) was estimated based on pile driving logs from another pile driving project at

Haines. Sound footprints were calculated for the installation of two piles (thus, accumulated over 1400 strikes). For vibratory pile driving, sound energy was accumulated for the two piles that could be installed or removed in a 24-hour period.

Modeled source levels and distances to NMFS acoustic thresholds based on these source levels and the sound propagation model are presented in Table 3 and 4.

**TABLE 3—IMPACT PILE DRIVING: MODELED SOURCE LEVELS AND HARASSMENT ZONES FOR IMPACT DRIVING TWO PILES PER DAY**  
[A dash indicates the threshold was not reached\*]

| Hearing group                                   | Level A threshold distance (R95%) (km) | Level A threshold area (km <sup>2</sup> ) | Level B (160 dB) threshold distance (km) | Level B threshold area (km <sup>2</sup> ) |
|---|--|---|--|---|
| <b>30 inch piles: modeled SL = 179.5 dB SEL</b> |  |   |  |   |
| Low-frequency cetacean .....                    | 1.65                                   | 3.17                                      | 1.98                                     | 4.52                                      |
| Mid-frequency cetacean .....                    | —                                      | —   |  |   |
| High-frequency cetacean .....                   | 1.45                                   | 1.13                                      |  |   |
| Phocid pinniped .....                           | 0.26                                   | 0.09                                      |  |   |
| Otarrid pinniped .....                          | —                                      | —   |  |   |
| <b>36 inch piles: modeled SL = 180.9 dB SEL</b> |  |   |  |   |
| Low-frequency cetacean .....                    | 2.04                                   | 4.78                                      | 2.67                                     | 6.79                                      |
| Mid-frequency cetacean .....                    | —                                      | —   |  |   |
| High-frequency cetacean .....                   | 1.49                                   | 2.17                                      |  |   |
| Phocid pinniped .....                           | 0.33                                   | 0.15                                      |  |   |
| Otarrid pinniped .....                          | —                                      | —   |  |   |

\* NMFS also considers peak sound pressure levels; however, in no case were these thresholds reached or greater than the SEL distances.

**TABLE 4—VIBRATORY PILE DRIVING: MODELED SOURCE LEVELS AND HARASSMENT ZONES FOR VIBRATORY DRIVING TWO PILES PER DAY**  
[A dash indicates the threshold was not reached\*]

| Hearing group                                   | Level A threshold Distance (R95%) (km) | Level A threshold area (km <sup>2</sup> ) | Level B (120 dB) threshold distance (km) | Level B threshold area (km <sup>2</sup> ) |
|---|--|---|--|---|
| <b>30 inch piles: modeled SL = 177.6 dB rms</b> |  |   |  |   |
| ALL .....                                       | -                                      | -   | 5.61                                     | 21.14                                     |
| <b>36 inch piles: modeled SL = 179.8 dB rms</b> |  |   |  |   |
| Low-frequency cetacean .....                    | 0.02                                   | <0.01                                     | 5.62                                     | 21.17                                     |
| Mid-frequency cetacean .....                    | —                                      | —   |  |   |
| High-frequency cetacean .....                   | —                                      | —   |  |   |
| Phocid pinniped .....                           | —                                      | —   |  |   |
| Otarrid pinniped .....                          | —                                      | —   |  |   |

\* NMFS also considers peak sound pressure levels; however, in no case were these thresholds reached or greater than the SEL distances.

The modeling approach described above and in ADOT&PF’s application constitutes a new approach in that it models both source levels and propagation loss to estimate distances to NMFS harassment thresholds. Some preliminary data comparing measured

sound levels to those produced by the models has been presented, but no peer reviewed analysis has been undertaken. To test the validity of the model, NMFS has included a proposed requirement that ADOT&PF conduct a source source verification (SSV) study upon the onset

of pile driving to validate the model or, if necessary, adjust the harassment zones based on measured data. This SSV study will also provide the first measurements of sound levels generated by 36-in piles driven by ADOT&PF. ADOT&PF has prepared a draft acoustic

monitoring plan which can be found at [www.nmfs.noaa.gov/pr/permits/incidental/construction.htm](http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm). We welcome comments on the ADOT&PF's source level modeling approach and the acoustic monitoring plan.

**Marine Mammal Occurrence**

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

The data on marine mammals in this area are diverse and fairly robust due mostly to ADF&G surveys. Strong seasonal occurrence of marine mammals in this area is well documented; therefore, density estimates for each species were calculated by month rather than averaged throughout the year. For example, we have already discussed the seasonality of Steller sea lions and how prey aggregations affect their abundance. Monthly Steller sea lion densities were calculated based on abundance surveys conducted at Gran Point (ADF&G, pers. comm). Considering the Steller sea lion data used to calculate density is from Gran

Point, ADOT&PF used this location to mark the southern boundary of the action area. The area from Gran Point north that encompasses Lutak Inlet and Lynn Canal is 91.3 km<sup>2</sup>; this area was used for all species' density estimates. For species other than Steller sea lion, average sighting rate was used to calculate density (*i.e.*, species occurrence rate per month/91.3km<sup>2</sup>). Harbor seals are generally present in the action area throughout the year, but their local abundance is clearly defined by the presence of available prey. During mid-March through mid-June, they are abundant in Lutak Inlet. For these months, an average of 100 seals per day in the inlet is considered a conservative estimate. For all other months, an estimate of 10 seals per month was incorporated into the density equation. Humpback whales are present in the action area from mid-April through June at a rate of five whales per month and given that a few whales have atypically remained in the area through the fall months (MOS 2016), we assumed two whales may

remain within the action area from August through November. Densities for killer whales were calculated assuming five animals enter the area seasonally from one of the resident or transient stocks, and may remain from April through November. Harbor porpoise may be present in low numbers (average of five per month) throughout the year. Finally, Dall's porpoise are not sighted very frequently but tend to travel in larger groups; therefore, ten animals per for the four months of construction were considered in the density calculations. Table 5 provides the resulting marine mammal densities for months when terminal construction would occur (again, no pile activities would occur from March 1 through May 31 to avoid peak marine mammal abundance and critical foraging periods). Although the table provides all relevant months, we used the months with highest density to calculate estimated take for each species, thus producing the most conservative estimates. Please refer to section 6.6.1 in ADOT's application for supporting data information.

**TABLE 5—MARINE MAMMAL DENSITY ESTIMATES (ANIMALS/KM<sup>2</sup>) DURING MONTHS WHEN PILE ACTIVITIES MAY OCCUR**

| Species                            | Jan   | Feb   | June  | July  | Aug   | Sept  | Oct   | Nov   | Dec   |
|------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Steller sea lion .....             | 2.06  | 1.87  | 17.65 | 1.35  | 0     | 0.01  | 1.85  | 1.59  | 2.47  |
| Harbor seal .....                  | 0.109 | 0.109 | 1.09  | 0.109 | 0.109 | 0.109 | 0.109 | 0.109 | 0.109 |
| Humpback whale .....               | 0     | 0     | 0.054 | 0.054 | 0.022 | 0.022 | 0.022 | 0.022 | 0     |
| Killer whale .....                 | 0     | 0     | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0     |
| Harbor porpoise .....              | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 | 0.054 |
| Dall's porpoise <sup>2</sup> ..... | 0     | 0     | 0     | 0.11  | 0.11  | 0.11  | 0.11  | 0     | 0     |

<sup>1</sup> The application and proposed IHA **Federal Register** notice incorrectly calculated a density of 7.55. No change to Steller sea lion takes result from this correction.

<sup>2</sup> For all months where Dall's porpoise may be present (July through October), the application and proposed IHA **Federal Register** notice incorrectly calculated a density of 0.03. Because Dall's porpoise take numbers are based on group size, this density increase warranted an increase to the number of groups, and therefore the number of takes, potentially exposed to noise about NMFS acoustic thresholds (see Table 6).

**Take Calculation and Estimation**

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

The following equation was used to calculate potential Level A take per species per pile type: *Level A harassment zone//pile type \* June density \* # of pile driving days/pile type*.

Also for Level B takes, we only considered the vibratory zone of 21.1 km<sup>2</sup>. In the proposed IHA notice, we had included calculations for the Level B harassment zone from impact pile driving but have since determined that this grossly overestimates take as the Level B zone for vibratory pile driving and removal essentially subsumes the Level B zone for impact hammering. As such, our Level B takes for all species, except those which are based on group

size, are reduced from the proposed IHA notice stage.

As described above, there would be 19 days of pile driving and 2 days of pile removal for a total of 21 pile activity days. We used the June density because, when densities changed throughout the year, this is when the highest density of all species occurs in the project area within the project in-water work window (with the exception of Dall's porpoise-see below) and ADOT&PF could conduct activities during this month. Therefore, the resulting take estimates assume all work is conducted in June, producing conservative estimates.

ADOT&PF may take 1.9 humpback whales by Level A harassment when impact driving 30" piles (*i.e.*, 3.17 km<sup>2</sup> \* 0.054 animals/km<sup>2</sup> \* 11 days). ADOT&PF may take 2.1 humpback whales by Level A harassment when

impact driving 36-in piles (*i.e.*, 4.78 km<sup>2</sup> \* 0.054 animals/km<sup>2</sup> \* 8 days).

Together, these equal 4 (*i.e.*, 1.9 from 30-in + 2.1 from 36") potential Level A takes (Table 6). However, humpback whales may travel in small groups (up to four animals per group); therefore, in the IHA we doubled this number to account for two groups of humpback whales for a total of eight Level A takes. Potential Level B takes from vibratory pile driving and removal (Level B area = 21.1 km<sup>2</sup>) was calculated using the equation described above: 21.1 km<sup>2</sup> \* 0.054 animals/km<sup>2</sup> \* 21 days = 24 animals. The IHA authorizes 24 Level B takes of humpback whales.

For killer whales, Level B takes from vibratory pile driving were calculated using June density and the full 21.1 km<sup>2</sup> Level B: 21.1 km<sup>2</sup> \* 0.054 animals/km<sup>2</sup> \* 21 days = 24 animals. However, the density used in the equation used in

ADOT&PF's application was based on transient killer whale average group size of 4–6 animals when a resident group can average 20 animals. Therefore, the IHA authorizes a total of 60 takes of killer whales to account for larger resident groups passing through the Level B harassment zone.

For Dall's porpoise, we increased the number of groups that may be within the calculated Level A thresholds area from one group in the proposed IHA notice to two groups to account for the increase in estimated density. We also increase the number of groups potentially exposed to noise levels about the Level B threshold to four groups. For Level B take, calculated take between 10 and 20 animals; therefore, we assumed two groups of ten each may occur within the Level B zone and are proposing to authorize 20 Level B takes.

Harbor porpoise take estimates were based on a density of .054 porpoise/km<sup>2</sup> with a Level A isopleth of 1.13 km<sup>2</sup> and 2.17 km<sup>2</sup> for impact pile driving 30-in (11 days) and 36-in (8 days) piles,

respectively. The resulting one take is less than the average group size of three animals. Further, harbor porpoise are cryptic species and could enter the Level A zone unnoticed during impact pile driving. Therefore, the IHA authorizes six Level A takes of harbor porpoise to account for missing animals. Level B take numbers for harbor porpoise were based on the conservative assumption four groups of porpoise could be exposed to noise levels at or above the Level B vibratory pile driving threshold for a total of 12 takes.

Harbor seals may linger in the area for multiple days; therefore, we conservatively estimate one harbor seal could be around the terminal on any given day for a total of 21 Level A takes. For Level B takes, we used the equation above using a density of 1.09 seals/km<sup>2</sup>. It is important to note that given harbor seals are more likely to haul-out and linger within the Level A and B harassment zone, it is more likely the take numbers represent exposures and

not individual seals. As with all other species, it is also likely animals will travel through the Level B zone heading up the inlet and then back down again. Because individual identification is not always possible, these separate sighting events would be counted as individual takes.

For Steller sea lions, no Level A takes are authorized. Level B takes from vibratory pile driving were calculated using the most conservative June density (assuming worst case scenario that all work occurs in June) and the full 21.1 km<sup>2</sup> Level B zone since no Level A takes are predicted: 21.1 km<sup>2</sup> \* 7.65 animals/km<sup>2</sup> \* 21 days = 3390 animals. Similar to harbor seals, this amount is not believed to be the number of individual Steller sea lions harassed but some lesser amount of individuals with repeated exposures.

Table 6 includes the total proposed take levels, by species, manner of taking, and the percentage of stock potentially taken by harassment.

TABLE 6—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND MONTH, RESULTING FROM IMPACT AND VIBRATORY PILE DRIVING

| Species          | Stock  | Stock size <sup>1</sup> | Level A         | Level B           | % of Stock            |
|------------------|--|-------------------------|-----------------|-------------------|-----------------------|
| Steller sea lion | eastern U.S.                                 | 60,131                  | 0               | <sup>2</sup> 3307 | 5.5                   |
|                  | western U.S.                                 | 49,497                  | 0               | <sup>2</sup> 83   | 0.17                  |
| Harbor Seal      | Lynn Canal/Stephens Passage                  | 9,478                   | 21              | 483               | 5.3                   |
| Humpback whale   | Central North Pacific                        | 10,103                  | <sup>3</sup> 4  | <sup>3</sup> 24   | 0.3                   |
| Killer whale     | Alaska Resident                              | 2,347                   | 0               | 60                | <sup>4</sup> 2.6–24.7 |
|                  | Northern Resident                            | 261                     | 0               |                   |                       |
|                  | Gulf of Alaska, Aleutian Islands, Bering Sea | 587                     | 0               |                   |                       |
|                  | West Coast Transient                         | 243                     | 0               |                   |                       |
| Harbor porpoise  | Southeast Alaska                             | 975                     | <sup>5</sup> 6  | 24                | 3.08                  |
| Dall's porpoise  | Alaska                                       | 83,400                  | <sup>5</sup> 20 | <sup>5</sup> 48   | 0.08                  |

<sup>1</sup> Stock size is N<sub>best</sub> according to NMFS 2016 Stock Assessment Reports.

<sup>2</sup> Calculated Level B take of all SSL's is based on a June density of 7.65 animals which equals 3390 individuals. We then subtracted the 83 animals which could belong to the western U.S. stock based a 2 percent distinction factor calculated from takes estimated in the proposed IHA Federal Register notice.

<sup>3</sup> Calculated Level A takes for humpback whales did not cover average group size; therefore, we are authorizing four takes. For ESA section 7 consultation purposes, 6.1 percent are designated to the Mexico DPS and the remaining are designated to the Hawaii DPS; therefore, we predict 2 Level B takes from the Mexico DPS.

<sup>4</sup> The percentages calculated here assume all 60 takes are from a single stock. It is unlikely all takes would be from the West Coast Transient stock; therefore, the percentage of the population taken is likely a gross overestimate.

<sup>5</sup> The calculated Level A take for harbor porpoise and Dall's porpoise is less than the average group size; therefore, we are proposing to authorize Level A take of two groups of each species (i.e., 6 and 20 animals, respectively). The calculated amount of Level B take for harbor porpoise is sufficient to cover multiple groups; therefore, we used the take equation.

**Mitigation**

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS

regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where

applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if

implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The following mitigation measures are included in the IHA:

- *Schedule*: No pile driving or removal would occur from March 1 through May 31 to avoid peak marine mammal abundance periods and critical foraging periods. In addition, the daily construction window for pile removal and driving shall begin no sooner than 30 minutes after sunrise and shall end no later than 30 minutes prior to sunset;

- *Pile Driving Delay/Shut-Down*: If an animal comes within 10 m (33 ft) of a pile being driven or removed, ADOT&PF would shut down. Pile driving activities would only be conducted during daylight hours when it is possible to visually monitor for marine mammals. If poor environmental conditions restrict visibility (e.g., from excessive wind or fog, high Beaufort state), pile installation would be delayed. If a species for which authorization has not been granted or if a species for which authorization has been granted but the authorized takes are met, ADOT&PF would delay or shut-down pile driving if the marine mammals approaches or is observed within the Level A and/or B harassment zone. In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as serious injury or mortality, the protected species observer (PSO) on watch would immediately call for the cessation of the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and NMFS Alaska Regional Office;

- *Soft-start*: For all impact pile driving, a “soft start” technique will be used at the beginning of each pile installation to allow any marine mammal that may be in the immediate area to leave before hammering at full energy. The soft start requires ADOT&PF to provide an initial set of three strikes from the impact hammer at 40 percent energy, followed by a one-minute waiting period, then two subsequent 3–strike sets. If any marine mammal is sighted within the Level A zone designated for that species prior to pile-driving, or during the soft start,

ADOT&PF will delay pile-driving until the animal is confirmed to have moved outside and on a path away from Level A zone or if 30 minutes have elapsed since the last sighting of a humpback whale or 15 minutes have elapsed since the last sighting of any other marine mammal species; and

- *Other best management practices*: ADOT&PF will drive all piles with a vibratory hammer to the maximum extent possible (i.e., until a desired depth is achieved or to refusal) prior to using an impact hammer; use the minimum hammer energy needed to safely install the piles; utilize sound attenuation devices (e.g., pile caps/cushions) to reduce source levels and, by association, received levels; and remove piles using a direct pull method instead of a vibratory hammer, if feasible. It is noted that although sound attenuation devices have proven effective at reducing source levels, because the actual amount of reduction of sound energy from using those devices is unknown, ADOT&PF and NMFS relied on unattenuated source levels to calculate harassment zones.

Based on our evaluation of the applicant’s proposed measures, as well as other measures considered by NMFS, we have determined that the proposed mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

### Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);

- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (e.g., source characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

- Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

- Mitigation and monitoring effectiveness.

### Visual Monitoring

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving and removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes.

A primary PSO would be placed at the terminal where pile driving would occur and a second observer would be placed at Tanani Point, located approximately 1 mi (1.6 km) southeast of the terminal. This second observer is at an advantage to observe species prior to entering the Level A zone as they move up Chilkoot Inlet, covering a majority of the Level B zone. PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld GPS or range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. The following measures also apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

(a) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;

(b) Advanced education in biological science or related field (undergraduate degree or higher required);

(c) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);

(d) Experience or training in the field identification of marine mammals, including the identification of behaviors;

(e) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(f) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and

(g) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal activities. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (e.g., percent cover, visibility);
- Water conditions (e.g., sea state, tide state);

- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- Other human activity in the area.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, ADOT&PF would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (e.g., Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with ADOT&PF to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. ADOT&PF would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that ADOT&PF discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (e.g., in less than a moderate state of decomposition as described in the next paragraph), ADOT&PF would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The

report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with ADOT&PF to determine whether modifications in the activities are appropriate.

In the event that ADOT&PF discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), ADOT&PF would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. ADOT&PF would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

#### *Acoustic Monitoring*

ADOT&PF relied on source level and sound propagation models to estimate Level A and harassment zones. To validate the outputs of these models, ADOT&PF will conduct acoustic monitoring during the first two days of pile driving. The acoustic monitoring plan is available for review at <http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm>. In summary, ADOT&PF will deploy three bottom-mounted Autonomous Multichannel Acoustic Recorders (AMARs) and conduct spot measurements with a hydrophone over the side of a vessel. The AMARs will be set 10 m, 1000 m and 5,000 m from the pile. Within one week, ADOT&PF will provide NMFS a report of their acoustic measurements. NMFS will review the report and if empirical data demonstrates adjustments to Level A and B take zones are warranted, those adjustments will be made.

#### **Negligible Impact Analysis and Determination**

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (i.e., population-level effects). An estimate of the number

of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.*, intensity, duration), the context of any responses (*e.g.*, critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

The Level A harassment zones identified in Tables 3 and 4 are based upon an animal exposed to impact pile driving two piles per day. Considering duration of impact driving each pile (up to 15 minutes) and breaks between pile installations (to reset equipment and move pile into place), this means an animal would have to remain within the area estimated to be ensonified above the Level A harassment threshold for multiple hours. This is highly unlikely given marine mammal movement throughout the area. If an animal was exposed to accumulated sound energy, the resulting PTS would likely be small (*e.g.*, PTS onset) at lower frequencies where pile driving energy is concentrated. Nevertheless, we propose authorizing a small amount of Level A take for four species which is considered in our analysis.

Behavioral responses of marine mammals to pile driving and removal at the Terminal, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities (as noted during modification to the Kodiak Ferry Dock) or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day and that pile driving and removal would occur on 21 days across 4 months, any harassment would be temporary. In addition, ADOT&PF would not conduct pile driving or removal during the

spring eulachon and herring runs as well as the fall salmon runs, when marine mammals are in greatest abundance and engaging in concentrated foraging behavior.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized.
- ADOT&PF would avoid pile driving and removal during peak periods of marine mammals abundance and foraging (*i.e.*, March 1 through May 31 eulachon and herring runs).
- ADOT&PF would implement mitigation measures such as vibratory driving piles to the maximum extent practicable, soft-starts, use of sound attenuation devices, and shut downs.
- Monitoring reports from similar work in Alaska have documented little to no effect on individuals of the same species impacted by the specified activities.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

#### Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is 0.03 to 12.3 percent of any stock's best population estimate. The 12.3 percent is based on the possibility all 30 takes of killer whales are from the West Coast Transient stock (population size 243) which is highly unlikely. The next lowest percent of stock is for the Steller sea lion eDPS at 6.7 percent;

however, this is also conservative because it assumes all pile driving occurs in June which has the highest Steller sea lion density and assumes all takes are of individual animals which is likely not the case. Harbor seal takes represent 6.3 percent of the Lynn Canal/Stephens passage population while takes for the remaining five species, including the Steller sea lion wDPS, represent less than 1 percent of all stocks.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

#### Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with NMFS Alaska Protected Resources Division Office, whenever we propose to authorize take for endangered or threatened species.

On October 20, 2017, NMFS Alaska Region issued a Biological Opinion to NMFS Office of Protected Resources and the Federal Highway Administration which concluded the Terminal Modification Project is not likely to jeopardize the continued existence of WDPS Steller sea lions or Mexico DPS humpback whales or adversely modify critical habitat because none exists within the action area.

#### Authorization

NMFS has issued an IHA to ADOT&PF for the potential harassment of small numbers of six marine mammal species incidental to pile driving and removal activities in Lutak Inlet, provided the previously mentioned mitigation, monitoring and reporting requirements are incorporated.

Dated: January 31, 2018.

#### Donna Wieting,

*Director, Office of Protected Resources,  
National Marine Fisheries Service.*

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**BILLING CODE 3510-22-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

[Docket No. CPSC–2018–0002]

**Agency Information Collection Activities; Proposed Collection; Comment Request; CPSC Playground Surfaces Survey****AGENCY:** Consumer Product Safety Commission.**ACTION:** Notice.

**SUMMARY:** The Consumer Product Safety Commission (CPSC or Commission) is announcing an opportunity for public comment on a new proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** for each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey that will assess children's potential exposure to playground surfaces, including recycled tire material.

**DATES:** Submit written or electronic comments on the collection of information by April 6, 2018.

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC–2018–0002, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Written Submissions:* Submit written submissions in the following way: Mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such

information should be submitted in writing.

*Docket:* For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC–2018–0002, into the “Search” box, and follow the prompts. A copy of the draft survey is available at <http://www.regulations.gov> under Docket No. CPSC–2018–0002, Supporting and Related Material.

**FOR FURTHER INFORMATION CONTACT:** Charu Krishnan, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: [CKrishnan@cpsc.gov](mailto:CKrishnan@cpsc.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency surveys. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. Accordingly, the CPSC is publishing notice of the proposed collection of information set forth in this document.

**A. Playground Surfaces Survey**

The Commission is authorized under section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that the Commission may conduct research, studies, and investigations on the safety of consumer products or test consumer products and develop product safety test methods and testing devices.

The use of recycled tire material or “tire crumb” rubber is commonplace for many athletic fields, as well as children's playgrounds. Playground surfaces derived from recycled tires are a popular option due to their low maintenance, variety of colors and designs, and ability to reduce the impacts from falls. The CPSC has received numerous inquiries from consumers and stakeholders regarding the safety of playground surfaces derived from recycled tires. In February 2016, the CPSC, the Environmental

Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC) launched the interagency Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds (Plan). One of the Plan's objectives is to identify the potential hazardous chemical exposure to children derived from recycled tire material used regularly on playgrounds throughout the United States. The EPA and CDC will evaluate the chemical hazards of recycled tire materials on athletic playing fields, and the CPSC will assess the level of risk and the extent to which children may be exposed to potential hazard(s) related to recycled tires on playgrounds.

As a first step, in 2016, the CPSC conducted focus groups to gather data from a small sample of parents, childcare providers, and personnel responsible for the inspection and maintenance of playgrounds on their experiences and observations of how children interact with various types of playground surfaces, including those derived from recycled tires.<sup>1</sup> Based on information obtained from these focus groups, the CPSC now proposes to conduct a survey of a nationally representative sample of parents or guardians of children (age 0 to 5) who visit playgrounds to gain a better understanding of potential exposures of playground surfaces on children, based on children's play behaviors on playgrounds. Exposure may include skin contact, ingestion, and potential contact through open wounds. With the data received from EPA and CDC regarding potential chemical hazards in recycled tires, and the information from the survey, CPSC staff plans to evaluate the extent children may be exposed to potential hazards related to tire crumb rubber and the level of risk from that exposure. This survey will help inform CPSC staff's analysis regarding playground surfaces derived from recycled tires. CPSC staff may also design future studies based on the information collected from the survey.

CPSC has contracted with the Fors Marsh Group, LLC (FMG) to design the survey. SSRS, LLC will program and administer the final survey. Trained interviewers will dial and conduct the survey using a computer-assisted telephone interview (CATI) system, in a secure location, to which only authorized personnel have access. Participants will be recruited by re-contacting respondents of the SSRS Omnibus. The SSRS Omnibus is a

<sup>1</sup> Approved by OMB under Control Number 3041–0136.

national, weekly, dual-frame bilingual RDD telephone survey designed to meet standards of quality associated with custom research studies. Each weekly wave of the SSRS Omnibus consists of 1,000 interviews; 600 are obtained with respondents on their cell phones, and approximately 35 interviews are completed in Spanish. The topic of the surveys varies week to week. Interviewers will conduct follow-up re-contacts to target specific populations on certain issues. We will use existing data from this sample source to pre-screen individuals in the target population (parents of children who are currently 0–5 years old). These targeted households will be re-contacted to administer the proposed survey. Participants will be re-screened at the beginning of the call to make sure that they meet the target criteria and to identify which subset of questions they will be given for the survey. Participation is voluntary and all responses will be kept confidential.

#### B. Burden Hours

Each telephone interview will take approximately 20 minutes to complete. We estimate the number of respondents to be 2,200. We estimate the total annual burden hours for respondents to be 726 hours. The monetized hourly cost is \$35.28, as defined by the average total hourly cost to employers for employee compensation for employees across all occupations as of June 2017, reported by the Bureau of Labor Statistics. Accordingly, we estimate the total annual cost burden to all respondents to be \$25,613. (726 hours × \$35.28 = \$25,613.28.). The total cost to the federal government for the contract to design and conduct the survey issued to FMG under contract number CPSC–D–16–0002 is \$243,593.

#### C. Request for Comments

The CPSC invites comments on these topics:

- Whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- The accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

**Alberta E. Mills,**

*Acting Secretary, Consumer Product Safety Commission.*

[FR Doc. 2018–02223 Filed 2–2–18; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID: DOD–2018–OS–0003]

### Proposed Collection; Comment Request

**AGENCY:** Defense Manpower Data Center, DoD.

**ACTION:** 60-Day information collection notice.

**SUMMARY:** In compliance with the *Paperwork Reduction Act of 1995*, the Defense Manpower Data Center announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by April 6, 2018.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09B, Alexandria, VA 22350–1700.

**Instructions:** All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any

personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Manpower Data Center (DMDC), DoD Center Monterey Bay, DBIDS, ATTN: David Schwab, Seaside, CA 93955, or call DMDC, DBIDS, at 831–583–2500.

#### SUPPLEMENTARY INFORMATION:

*Title; Associated Form; and OMB Number:* Defense Biometrics Identification System; DBIDS Registration Application; OMB Control Number 0704–0455.

*Needs and Uses:* The information collection requirement is necessary to obtain and record the biographic & biometric data connected with positively identifying identity, eligibility for access, and fitness within DBIDS and shared with IMESA/IOLS. The form data is used in the determination of access at DBIDS sites and affiliated systems through use of IMESA/IOLS.

*Affected Public:* The primary public entity are individuals with secondary entities being: The Federal Government, Business or other for profits, Not-For-Profit Institutions, and State, Local or Tribal Government seeking access to Controlled Federal Government locations.

*Annual Burden Hours:* 291,667.

*Number of Respondents:* 2,500,000.

*Responses per Respondent:* 1.

*Annual Responses:* 2,500,000.

*Average Burden per Response:* 7 minutes.

*Frequency:* On occasion.

Respondents are those persons requiring access to DOD Installations who do not meet requirements to possess a DOD identification card. Their data is collected pursuant to DoD force protection measures and base security policy. Persons possessing a valid DOD identification card have their data automatically provided through system to system interfaces and are not considered burdened.

Dated: January 31, 2018.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison  
Officer, Department of Defense.*

[FR Doc. 2018-02213 Filed 2-2-18; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### Policy and Procedural Guidance for Processing Requests To Alter U.S. Army Corps of Engineers Civil Works Projects Pursuant to Section 408

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice.

**SUMMARY:** The U.S. Army Corps of Engineers (USACE) is proposing to issue an Engineer Circular (EC), which is an agency policy document that will provide the policies and procedures related to how USACE will process certain requests by others to alter a USACE civil works project pursuant to Section 14 of the Rivers and Harbors Act of 1899, as amended (more commonly referred to as Section 408). This notice announces the availability of the draft EC for comment. The comment period on the draft document starts with the publication of this notice in the **Federal Register** and will last for 30 days. The draft EC is available for review on the USACE Section 408 website (<http://www.usace.army.mil/Missions/Civil-Works/Section408/>) and at <http://www.regulations.gov> reference docket number COE-2018-0003.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** You may submit comments identified by docket number COE-2018-0003 by any of the following methods:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Email:* [HQ-Section408@usace.army.mil](mailto:HQ-Section408@usace.army.mil) and include the docket number COE-2018-0003 or "EC 1165-2-220 Comments" in the subject line of the message.

*Mail:* Headquarters, U.S. Army Corps of Engineers, ATTN: CECW-CE/3E62, 441 G Street NW, Washington, DC 20314-1000.

*Hand Delivery/Courier:* Due to security requirements, we cannot receive comments by hand delivery or courier.

*Instructions:* If submitting comments through the Federal eRulemaking Portal, direct your comments to docket number

COE-2018-0003. All comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to USACE without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov). All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

**FOR FURTHER INFORMATION CONTACT:** Ms. Tammy Conforti at 202-761-4649, email [HQ-Section408@usace.army.mil](mailto:HQ-Section408@usace.army.mil), or visit <http://www.usace.army.mil/Missions/Civil-Works/Section408/>.

**SUPPLEMENTARY INFORMATION:** Section 14 of the Rivers and Harbors Act of 1899, as amended, and codified in 33 U.S.C. 408 (Section 408) provides that the Secretary of the Army may, upon the recommendation of the Chief of Engineers, grant permission to other entities for the permanent or temporary alteration or use of any USACE Civil Works project. This requires a determination by the Secretary that the requested alteration will not be

injurious to the public interest and will not impair the usefulness of the USACE project.

USACE is proposing to issue Engineer Circular (EC) 1165-2-220, Policy and Procedural Guidance for Processing Requests to Alter U.S. Army Corps of Engineers Civil Works Projects Pursuant to 33 U.S.C. 408, to update processes related to how USACE will review certain requests by others to alter a USACE civil works project. For example, other entities may want to alter a Civil Works project to increase recreational opportunities; improve flood risk management; or construct a road, transmission line, or pipeline across a Civil Works project. The purpose of the Section 408 review is to ensure that the Congressionally-authorized purpose and benefits of a Civil Works project are protected and maintained (e.g., flood risk management, navigation, coastal storm damage reduction) and to ensure what is being proposed is not injurious to the public interest. An effective and efficient review of proposed alterations to Civil Works projects protects taxpayer investments in water resources infrastructure, while ensuring compatibility with new infrastructure, improvements, and other public or private interests.

The first comprehensive policy and procedures for evaluation of alterations under Section 408 was issued as EC 1165-2-216 on July 31, 2014. Based on lessons learned from implementing EC 1165-2-216, USACE began the process to revise and update its Section 408 process to clarify applicability, roles and responsibilities, and the basic requirements. From November 2016 through January 2018, USACE issued multiple interim guidance to improve the efficiency and effectiveness of the Section 408 review process while continuing to work on a full policy revision.

USACE has now completed a draft of a new policy document (EC 1165-2-220) to replace EC 1165-2-216. EC 1165-2-220 would expire two years from issuance, which will provide USACE time to consider implementation experience to identify any necessary clarifications or changes. After two years, EC 1165-2-220 will either be revised, rescinded, or converted to an Engineer Regulation, which does not expire.

EC 1165-2-220 is intended to consolidate the interim guidance issued since 2016 and update procedures to facilitate a scalable approach to reviewing Section 408 requests in a timely manner while maintaining a national consistent approach to

decision-making. EC 1165–2–220 includes proposed revisions that clarify the geographical limits for when the procedures set forth in the EC for processing a Section 408 permission apply; eliminates duplication of effort when the intent of Section 408 can be satisfied by another existing USACE review process; addresses emergency alterations; and, provides additional detail on categorical permissions and an option for conducting a multi-phased review. The EC also provides greater clarity on requirements for environmental compliance; implements timelines for USACE reviews and notifications; and, provides additional delegation of decision-making authority.

EC 1165–2–220 has also been developed in accordance with requirements in Section 1007 of the Water Resources Reform and Development Act (WRRDA) of 2014 (Pub. L. 113–121) and Section 1156 of the Water Resources Development Act (WRDA) of 2016 (Title I of Pub. L. 114–322). USACE now invites all interested parties to review and provide comment on the draft of EC 1165–2–220 prior to final publication.

Following the comment period, USACE will consider all comments received, make revisions as needed, and publish the final EC 1165–2–220 as soon as possible. When the final EC is published, a notice will be placed in the **Federal Register**. The final EC will be available on USACE publications website (<http://www.publications.usace.army.mil/>).

Dated: January 31, 2018.

**James C. Dalton,**

*Director of Civil Works.*

[FR Doc. 2018–02207 Filed 2–2–18; 8:45 am]

BILLING CODE 3720–58–P

## DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0007]

### Agency Information Collection Activities; Comment Request; Teacher Education Assistance for College and Higher Education Grant Program (TEACH Grant Program) Agreement To Serve

**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before April 6, 2018.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2018–ICCD–0007. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Jon Utz, 202–377–4040.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Teacher Education Assistance for College and Higher Education Grant Program (TEACH Grant Program) Agreement to Serve.

*OMB Control Number:* 1845–0083.

*Type of Review:* A revision of an existing information collection.

*Respondents/Affected Public:* Individuals or Households.

*Total Estimated Number of Annual Responses:* 50,793.

*Total Estimated Number of Annual Burden Hours:* 25,397.

**Abstract:** As a condition for receiving a TEACH Grant, a student must sign an Agreement to Serve. A new Agreement to Serve must be signed for each award year during which a student wishes to receive a TEACH Grant. By signing the Agreement to Serve, a TEACH Grant recipient agrees to meet the teaching service obligation and other terms and conditions of the TEACH Grant Program that are described in the Agreement to Serve. In accordance with these terms and conditions, if a TEACH Grant recipient does not fulfill the required teaching service obligation or otherwise fails to meet the requirements of the TEACH Grant Program, any TEACH Grant funds the individual received will be converted to a Direct Unsubsidized Loan that the grant recipient must repay in full, with interest. The Agreement to Serve also explains the repayment terms and conditions that will apply if a TEACH Grant is converted to a Direct Unsubsidized Loan.

Dated: January 31, 2018.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–02232 Filed 2–2–18; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF EDUCATION

### Applications for New Awards; Native American Career and Technical Education Program

**AGENCY:** Office of Career, Technical, and Adult Education, Department of Education.

**ACTION:** Notice.

**SUMMARY:** The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2018 for the Native American Career and Technical Education Program (NACTEP), Catalog of Federal Domestic Assistance (CFDA) number 84.101A.

**DATES:**

*Applications Available:* February 5, 2018.

*Deadline for Transmittal of Applications:* March 19, 2018.

**FOR FURTHER INFORMATION CONTACT:**

Gwen Washington, U.S. Department of

Education, 400 Maryland Avenue SW, Room 11076, Potomac Center Plaza, Washington, DC 20202-7241. Telephone: (202) 245-7790 or by fax at (202) 245-7170. Or Linda Mayo, U.S. Department of Education, 400 Maryland Avenue SW, Room 11075, Potomac Center Plaza, Washington, DC 20202-7241. Telephone: (202) 245-7792. Fax: (202) 245-7170.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1-800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### Full Text of Announcement

##### I. Funding Opportunity Description

*Purpose of Program:* NACTEP provides grants to improve career and technical education (CTE) programs that are consistent with the purposes of the Carl D. Perkins Career and Technical Education Act of 2006 (the Act) and that benefit Native Americans and Alaska Natives.

*Background:* This notice invites applications for a NACTEP competition that implements section 116 of the Act, enacted August 12, 2006. Section 116 of the Act authorizes the Secretary to award grants to, or enter into cooperative agreements or contracts with, Indian Tribes, Tribal organizations, and Alaska Native entities to operate CTE projects that improve CTE for Native American and Alaska Native students.

Under section 116 of the Act, Bureau-funded schools (as defined in this notice) proposing to fund secondary programs are not eligible to receive an award directly from the Secretary. However, an Indian Tribe, Tribal organization, Alaska Native entity, or Bureau-funded school may use its award to assist a secondary school operated or supported by the U.S. Department of the Interior to carry out CTE programs. A Bureau-funded school that is not proposing a secondary program is eligible for assistance under NACTEP.

*Priority:* Under this competition we are particularly interested in applications that address the following priority.

*Invitational Priority:* For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

##### **Creating or Expanding Opportunities for Individuals To Obtain Recognized Postsecondary Credentials in Science, Technology, Engineering, Mathematics, or Computer Science**

For the purposes of this invitational priority, *computer science* means the study of computers and algorithmic processes and includes the study of computing principles and theories, computational thinking, computer hardware, software design, coding, analytics, and computer applications.

Computer science includes computer programming or coding as a tool to create software, including applications, games, websites, and tools to manage or manipulate data; or development and management of computer hardware and the other electronics related to sharing, securing, and using digital information.

In addition to coding, the expanding field of computer science also includes computational thinking and interdisciplinary problem-solving to equip students with the skills and abilities necessary to apply computation in our digital world.

Computer science does not include using a computer for everyday activities, such as browsing the internet; use of tools like word processing, spreadsheets, or presentation software; or using computers in the study and exploration of unrelated subjects.

*Requirements:* These application and program requirements are from the notice of final requirements, definitions, and selection criteria for this program (Notice of Final Requirements), published in the **Federal Register** on February 26, 2013 (78 FR 12955), unless a specific statutory citation for the requirement is provided.

The application requirements are:

(1) An eligible applicant (as determined by the Act) must include documentation in its application showing that it and, if appropriate, its consortium members are eligible to apply.

As defined in the Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 5304(l)), the term “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, That in any case where a contract is let or grant made to an

organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. In accordance with this statutory definition, any Tribal organization proposing to provide NACTEP services for the benefit of more than one Indian Tribe must first obtain the approval of each Indian Tribe it proposes to serve and must submit documentation of such approval with its NACTEP application and that documentation of Tribal approval is a prerequisite to the awarding of a NACTEP grant to any Tribal organization proposing to serve more than one Indian Tribe.

(2) An applicant that is not proposing to provide CTE directly to its students and proposes instead to use NACTEP funds to pay one or more qualified educational entities to provide education to its students must include with its application a written CTE agreement between the applicant and that entity. The written agreement must describe the commitment between the applicant and each educational entity and must include, at a minimum, a statement of the responsibilities of the applicant and the entity. The agreement must be signed by the appropriate individuals on behalf of each party, such as the authorizing official or president of a Tribe or Tribal organization, a college president, or a college dean.

The program requirements are:

##### *Requirement 1—Authorized Programs*

(a) Section 116(e) of the Act requires the Secretary to ensure that activities funded under NACTEP “will improve career and technical education programs” (20 U.S.C. 2326(e)). Therefore, under NACTEP the Assistant Secretary will award grants to carry out projects that—

(1) Propose organized educational activities offering a sequence of courses that—

(i) Provide individuals with coherent and rigorous content aligned with challenging academic standards and relevant technical knowledge and skills needed to prepare for further education and careers in current or emerging professions;

(ii) Provide technical skill proficiency, an industry-recognized credential, a certificate, or an associate degree; and

(iii) Include competency-based applied learning that contributes to the academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, general employability skills, technical skills, and occupation-

specific skills, and knowledge of all aspects of an industry, including entrepreneurship, of an individual. Projects may include prerequisite courses (other than remedial courses) that meet the definitional requirements of section 3(5) of the Act. (20 U.S.C. 2302(5)). In addition, at the secondary level, coherent and rigorous academic curriculum must be aligned with challenging academic content standards and student academic achievement standards in reading or language arts and in mathematics that the State in which the applicant is located has established under the Elementary and Secondary Education Act of 1965 (ESEA). Contacts for State ESEA programs may be found on the internet at: [www.ed.gov/about/contacts/state/index.html](http://www.ed.gov/about/contacts/state/index.html).

(2) Develop new programs, services, or activities or improve or expand existing programs, services, or activities that are consistent with the purposes of the Act. In other words, the Department will support “expansions” or “improvements” that include, but are not limited to, the expansion of effective programs or practices; upgrading of activities, equipment, or materials; increasing staff capacity; adoption of new technology; modification of curriculum; or implementation of new policies to improve program effectiveness and outcomes.

(3) Fund a CTE program, service, or activity that—

(i) Is a new program, service, or activity that was not provided by the applicant during the instructional term (a defined period, such as a semester, trimester, or quarter, within the academic year) that preceded the request for funding under NACTEP;

(ii) Will improve or expand an existing CTE program; or

(iii) Inherently improves CTE.

**Note:** A program, service, or activity “inherently improves CTE” if it—

(a) Develops new CTE programs of study that will be approved by the appropriate accreditation agency;

(b) Strengthens the rigor of the academic and career and technical components of funded programs;

(c) Uses curriculum that is aligned with industry-recognized standards and will result in students attaining industry-recognized credentials, certificates, or degrees;

(d) Integrates academics (other than remedial courses) with CTE programs through a coherent sequence of courses to ensure learning in the core academic and career and technical subjects;

(e) Links CTE at the secondary level with CTE at the postsecondary level and facilitates students’ pursuit of a baccalaureate degree;

(f) Expands the scope, depth, and relevance of curriculum, especially content that

provides students with a comprehensive understanding of all aspects of an industry and a variety of hands-on, job-specific experiences; and

(g) Offers—

(1) Work-related experience, internships, cooperative education, school-based enterprises, entrepreneurship, community service learning, and job shadowing that are related to CTE programs;

(2) Coaching/mentoring, support services, and extra help for students after school, on weekends, and/or during the summers, so they can meet higher standards;

(3) Career guidance and academic counseling for students participating in CTE programs;

(4) Placement services for students who have successfully completed CTE programs and attained a technical skill proficiency that is aligned with industry-recognized standards;

(5) Professional development programs for teachers, counselors, and administrators;

(6) Strong partnerships among grantees and local educational agencies, postsecondary institutions, community leaders, adult education providers, and, as appropriate, other entities, such as employers, labor organizations, parents, and local partnerships, to enable students to achieve State academic standards and career and technical skills;

(7) The use of student assessment and evaluation data to improve continually instruction and staff development with the goal of increasing student achievement in CTE programs; or

(8) Research, development, demonstration, dissemination, evaluation and assessment, capacity-building, and technical assistance, related to CTE programs.

(b) Assistance to Bureau-funded secondary schools. An Indian Tribe, a Tribal organization, or an Alaska Native entity that receives funds through a NACTEP grant or contract may use the funds to provide assistance to a secondary school operated or supported by the U.S. Department of the Interior to enable such school to carry out CTE programs. (Section 116(b)(3) of the Act)

#### *Requirement 2—Evaluation*

To help ensure the high quality of NACTEP projects and the achievement of the goals and purposes of section 116 of the Act, each grantee must budget for and conduct an ongoing evaluation of the effectiveness of its NACTEP project. An independent evaluator must conduct the evaluation. The evaluation must be appropriate for the project and be both formative and summative in nature.

#### *Requirement 3—Student Stipends*

In accordance with section 116(c)(2) of the Act, a portion of an award under this program may be used to provide stipends (as defined in the Definitions section of this notice) to one or more students to help meet the students’ costs of participation in a NACTEP project. A

grantee must apply the following procedures for determining student eligibility for stipends and appropriate amounts to be awarded as stipends:

(1) To be eligible for a stipend a student must—

(i) Be enrolled in a CTE project funded under this program;

(ii) Be in regular attendance in a NACTEP project and meet the training institution’s attendance requirement;

(iii) Maintain satisfactory progress in his or her program of study according to the training institution’s published standards for satisfactory progress; and

(iv) Have an acute economic need that—

(A) Prevents participation in a project funded under this program without a stipend; and

(B) Cannot be met through a work-study program.

(2) The amount of a stipend is the greater of either the minimum hourly wage prescribed by State or local law or the minimum hourly wage established under the Fair Labor Standards Act.

(3) A grantee may only award a stipend if the stipend combined with other resources the student receives does not exceed the student’s financial need. A student’s financial need is the difference between the student’s cost of attendance and the financial aid or other resources available to defray the student’s cost of participating in a NACTEP project.

(4) To calculate the amount of a student’s stipend, a grantee would multiply the number of hours a student actually attends CTE instruction by the amount of the minimum hourly wage that is prescribed by State or local law, or by the minimum hourly wage that is established under the Fair Labor Standards Act.

*Example:* If a grantee uses the Fair Labor Standards Act minimum hourly wage of \$7.25 and a student attends classes for 20 hours a week, the student’s stipend would be \$145 for the week during which the student attends classes ( $\$7.25 \times 20 = \$145.00$ ).

**Note:** In accordance with applicable Department statutory requirements and administrative regulations, grantees must maintain records that fully support their decisions to award stipends and the amounts that are paid, such as proof of a student’s enrollment in a NACTEP project, stipend applications, timesheets showing the number of attendance hours confirmed in writing by an instructor, student financial status information, and evidence that a student would not be able to participate in the NACTEP project without a stipend. (20 U.S.C. 1232f; 34 CFR 75.700–75.702; 75.730; and 75.731)

(5) An eligible student may receive a stipend when taking a course for the

first time. However, generally a stipend may not be provided to a student who has already taken, completed, and had the opportunity to benefit from a course and is merely repeating the course.

(6) An applicant must include in its application the procedure it intends to use to determine student eligibility for stipends and stipend amounts, and its oversight procedures for the awarding and payment of stipends.

#### *Requirement 4—Direct Assistance to Students*

A grantee may provide direct assistance to students if the following conditions are met:

(1) The recipient of the direct assistance is an individual who is a member of a special population and who is participating in the grantee's NACTEP project.

(2) The direct assistance is needed to address barriers to the individual's successful participation in that project.

(3) The direct assistance is part of a broader, more generally focused program or activity to address the needs of an individual who is a member of a special population.

**Note:** Direct assistance to individuals who are members of special populations is not, by itself, a "program or activity for special populations."

(4) The grant funds used for direct assistance must be expended to supplement, and not supplant, assistance that is otherwise available from non-Federal sources. (20 U.S.C. 2391(a)). For example, generally, a postsecondary educational institution could not use NACTEP funds to provide child care for single parents if non-Federal funds previously were made available for this purpose, or if non-Federal funds are used to provide child care services for single parents participating in non-CTE programs and these services otherwise would have been available to CTE students in the absence of NACTEP funds.

(5) In determining how much of the NACTEP grant funds it will use for direct assistance to an eligible student, a grantee must consider whether the specific services to be provided are a reasonable and necessary cost of providing CTE programs for special populations. However, the Assistant Secretary does not envision a circumstance in which it would be a reasonable and necessary expenditure of NACTEP project funds for a grantee to use a majority of a project's budget to pay direct assistance to students, in lieu of providing the students served by the project with CTE.

#### *Requirement 5—Appeal Process*

Any applicant denied funding under this NACTEP competition may request a hearing to review the Secretary's decision not to make the award. The Secretary will implement the appeal process in accordance with the procedures set forth in 34 CFR 401.23. In accordance with those procedures, any applicant denied funding will have 30 calendar days to make a written request to the Secretary for a hearing to review the Secretary's decision. (25 U.S.C. 5321(b)).

#### *Requirement 6—Integration of Services*

Section 116(f) of the Act provides that a Tribe, Tribal organization, or Alaska Native entity receiving financial assistance under this program may integrate those funds with assistance received from related programs in accordance with the provisions of Public Law 102-477, the Indian Employment, Training and Related Services Demonstration Act of 1992 (25 U.S.C. 3401 *et seq.*). An entity wishing to integrate funds must have a plan that meets the requirements of the Indian Employment, Training and Related Services Demonstration Act and is acceptable to the Secretary of the Interior and the Secretary of Education.

For further information on the integration of grant funds under this and related programs contact Terrence Parks, the Division of Workforce Development, Office of Indian Services, Bureau of Indian Affairs, U.S. Department of the Interior, 1951 Constitution Avenue NW, Mailstop 20 SIB, Washington, DC 20245. Telephone: (202) 513-7625. Email: [Terrence.parks@bia.gov](mailto:Terrence.parks@bia.gov). Fax: (202) 208-4564.

#### *Requirement 7—Indian Self-Determination Contracts*

Section 116(b)(2) of the Act provides that grants or contracts awarded under section 116 of the Act are subject to the terms and conditions of section 102 of the ISDEAA (25 U.S.C. 5321) and must be conducted in accordance with the provisions of sections 4, 5, and 6 of the Act of April 16, 1934 (25 U.S.C. 5345-5347), that are relevant to the programs administered under section 116(b) of the Act. Section 102 of the ISDEAA authorizes Indian Tribes to request self-determination contracts from the Department of Interior. Accordingly, an Indian Tribe or Tribal organization that has applied to the Secretary for financial assistance under NACTEP and has been notified of its selection to be a recipient of financial assistance may submit a request to both the Secretary of Education (via the contact person listed

under **FOR FURTHER INFORMATION CONTACT**) and the relevant Department of Interior contact person to operate its NACTEP project through a section 102 Indian self-determination contract.

After successful applicants are selected under this NACTEP competition, the Secretary will review any requests to operate a project under an Indian self-determination contract pursuant to the ISDEAA. If a request for an Indian self-determination contract is approved, the Indian Tribe or Tribal organization submitting the request will be required, to the extent possible, to operate its project in accordance with the ISDEAA, relevant provisions in sections 4, 5, and 6 of the Act of April 16, 1934 (25 U.S.C. 5345-5347), the Act, and the non-statutory program requirements specified in this notice.

The CTE programs provided through an Indian self-determination contract would have to be essentially the same as were proposed in the initial application and approved by the Department. Any Indian Tribe or Tribal organization that is selected to receive funding under this competition, but whose request to operate the project under an Indian self-determination contract is denied, may appeal the denial to the Secretary. If you have questions about ISDEAA self-determination contracts, please contact the persons listed under **FOR FURTHER INFORMATION CONTACT**.

*Definitions:* These definitions are from statute, 34 CFR 400.4, and the Notice of Final Requirements. The source of each definition is noted after the definition.

*Act of April 16, 1934* means the Federal law commonly known as the "Johnson-O'Malley Act" that authorizes the Secretary of the Interior to enter into contracts for the education of Indians and other purposes. (25 U.S.C. 5345-5347)

*Acute economic need* means an income that is at or below the national poverty level according to the latest available data from the U.S. Department of Commerce or the U.S. Department of Health and Human Services Poverty Guidelines. (Notice of Final Requirements)

*Alaska Native or Native* means a citizen of the United States who is a person of one-fourth degree or more Alaska Indian (including Tsimshian Indians not enrolled in the Metlakta Indian Community<sup>1</sup>) Eskimo, or Aleut

<sup>1</sup> The correct name of this community is Metlakatla Indian Community. It is misspelled in the Alaska Native Claims Settlement Act, which is the source of this definition.

blood, or a combination thereof. The term includes—

(a) Any Native, as so defined, either or both of whose adoptive parents are not Natives; and

(b) In the absence of proof of a minimum blood quantum, any citizen of the United States who is regarded as an Alaska Native by the Native village or Native group of which he or she claims to be a member and whose father or mother is (or, if deceased, was) regarded as Native by any village or group. Any decision of the Secretary of the Interior regarding eligibility for enrollment will be final. (20 U.S.C. 2326(a)(1); 43 U.S.C. 1602(b))

*Alaska Native entity* means an entity such as an Alaska Native village, group, or regional or village corporation. (43 U.S.C. 1601 *et seq.*)

*Alaska Native group* means any Tribe, band, clan, village, community, or village association of Natives in Alaska composed of less than twenty-five Natives, who comprise a majority of the residents of the locality. (43 U.S.C. 1602(d))

*Alaska Native village* means any Tribe, band, clan, group, village, community, or association in Alaska listed in sections 1610 and 1615 of the Alaska Native Claims Settlement Act, or that meets the requirements of chapter 33 of the Alaska Native Claims Settlement Act, and that the Secretary of the Interior determines was, on the 1970 census enumeration date (as shown by the census or other evidence satisfactory to the Secretary of the Interior, who shall make findings of fact in each instance), composed of twenty-five or more Natives. (43 U.S.C. 1602(c))

*Alaska regional corporation* means an Alaska Native regional corporation established under the laws of the State of Alaska in accordance with the provisions of chapter 33 of the Alaska Native Claims Settlement Act. (43 U.S.C. 1602(g))

*Alaska village corporation* means an Alaska Native village corporation organized under the laws of the State of Alaska as a business for profit or nonprofit corporation to hold, invest, manage and/or distribute lands, property, funds, and other rights and assets for and on behalf of an Alaska Native village, in accordance with the terms of chapter 33 of the Alaska Native Claims Settlement Act. (43 U.S.C. 1602(j))

*Bureau* means the Bureau of Indian Affairs of the U.S. Department of the Interior. (25 U.S.C. 2021(2))

*Bureau-funded school* means—

(a) A Bureau-operated elementary or secondary day or boarding school or Bureau-operated dormitory for students

attending a school other than a Bureau school. (25 U.S.C. 2021(3) and (4));

(b) An elementary school, secondary school, or dormitory that receives financial assistance for its operation under a contract, grant, or agreement with the Bureau under section 102, 103(a), or 208 of the ISDEAA (25 U.S.C. 5321, 5322(a), or 5355) or under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2504 *et seq.*). (25 U.S.C. 2021(3) and (5)); or

(c) A school for which assistance is provided under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2501 *et seq.*). (25 U.S.C. 2021(3))

*Career and technical education (CTE)* means organized educational activities that—

(a) Offer a sequence of courses that—

(1) Provides individuals with coherent and rigorous content aligned with challenging academic standards and relevant technical knowledge and skills needed to prepare for further education and careers in current or emerging professions;

(2) Provides technical skills proficiency, an industry-recognized credential, a certificate, or an associate degree; and

(3) May include prerequisite courses (other than a remedial course) that meet the requirements of this definition; and

(b) Include competency-based applied learning that contributes to the academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, general employability skills, technical skills, and occupation-specific skills, and knowledge of all aspects of an industry, including entrepreneurship, of the individual. (20 U.S.C. 2302(5))

*Coherent sequence of courses* means a series of courses in which vocational<sup>2</sup> and academic education are integrated, and that directly relates to, and leads to, both academic and occupational competencies. The term includes competency-based education, academic education, and adult training or retraining, including sequential units encompassed within a single adult retraining course, that otherwise meet the requirements of this definition. (34 CFR 400.4)

*Direct assistance to students* means tuition, dependent care, transportation, books, and supplies that are necessary for a student to participate in a project funded under this program. (Notice of Final Requirements)

*Indian* means a person who is a member of an Indian Tribe. (20 U.S.C. 2326(a)(3); 25 U.S.C. 5304(d))

<sup>2</sup> As a result of the passage of the Act, the term “vocational education” has been updated to “career and technical education.”

*Indian Tribe* means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. (20 U.S.C. 2326(a)(3); 25 U.S.C. 5304(e))

*Institution of higher education* means—

(a) An educational institution in any State that—

(1) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate;

(2) Is legally authorized within such State to provide a program of education beyond secondary education;

(3) Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association or, if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the Secretary of Education for the granting of pre-accreditation status, and the Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

(b) The term also includes—

(1) Any school that provides not less than a 1-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provisions of paragraphs (a)(1), (2), (4), and (5) of this definition.

(2) A public or nonprofit private educational institution in any State that, in lieu of the requirement in paragraph (a)(1) of this definition, admits as regular students persons who are beyond the age of compulsory school attendance in the State in which the institution is located. (20 U.S.C. 1001 and 2302(18))

*Special populations* means—

(a) Individuals with disabilities;

(b) Individuals from economically disadvantaged families, including foster children;

(c) Individuals preparing for nontraditional fields;

(d) Single parents, including single pregnant women;

(e) Displaced homemakers; and  
(f) Individuals with limited English proficiency. (20 U.S.C. 2302(29))

*Stipend* means a subsistence allowance for a student that is necessary for the student to participate in a project funded under this program. (Notice of Final Requirements)

*Support services* means services related to curriculum modification, equipment modification, classroom modification, supportive personnel, and instructional aids and devices. (20 U.S.C. 2302(31))

*Tribal organization* means the recognized governing body of any Indian Tribe; any legally established organization of Indians that is controlled, sanctioned, or chartered by such governing body or that is democratically elected by the adult members of the Indian community to be served by such organization and that includes the maximum participation of Indians in all phases of its activities: Provided, That, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. (20 U.S.C. 2326(a)(3); 25 U.S.C. 5304(l))

*Tribally controlled college or university* means an institution of higher education that is formally controlled, or has been formally sanctioned, or chartered, by the governing body of an Indian Tribe or Tribes, except that no more than one such institution shall be recognized with respect to any such Tribe. (20 U.S.C. 2302(33) and 25 U.S.C. 1801(a)(4))

**Program Authority:** 20 U.S.C. 2301, *et seq.*, particularly 2326(a)–(g).

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of

the Department in 2 CFR part 3474 including 2 CFR 3474.20. (d) The Notice of Final Requirements.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

## II. Award Information

*Type of Award:* Discretionary grants.

*Estimated Available Funds:*

\$13,764,000 for the first 12 months of the project period. Funding for years two and three is subject to the availability of funds and to a grantee meeting the requirements of 34 CFR 75.253. Contingent upon the availability of funds and the quality of applications, we may make additional awards later in FY 2018 or in subsequent years from the list of unfunded applications from this competition.

*Estimated Range of Awards:* \$300,000 to \$500,000.

*Estimated Average Size of Awards:* \$458,800.

*Estimated Number of Awards:* 30.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 36 months. The Secretary may extend the performance periods of funded NACTEP grantees for an additional two years, should Congress continue to appropriate funds under the Act.

## III. Eligibility Information

1. *Eligible Applicants:* (a) The following entities are eligible to apply under this competition:

(1) A federally recognized Indian Tribe.

(2) A Tribal organization.

(3) An Alaska Native entity.

(4) A Bureau-funded school, except for a Bureau-funded school proposing to use its award to support secondary school CTE programs.

(b) Any Tribe, Tribal organization, Alaska Native entity, or eligible Bureau-funded school may apply individually or as part of a consortium with one or more eligible Tribes, Tribal organizations, Alaska Native entities, or eligible Bureau-funded schools. (Eligible applicants seeking to apply for funds as a consortium must meet the requirements in 34 CFR 75.127–75.129, which apply to group applications.)

2. (a) *Cost Sharing or Matching:* This program does not require cost sharing or matching.

(b) *Supplement-Not-Supplant:* This program involves supplement-not-supplant funding requirements. In accordance with section 311(a) of the Act, funds under this program may not be used to supplant non-Federal funds used to carry out CTE activities. Further,

the prohibition against supplanting also means that grantees are required to use their negotiated restricted indirect cost rates under this program. (34 CFR 75.563)

We caution applicants not to plan to use funds under NACTEP to replace otherwise available non-Federal funding for direct assistance to students and family assistance programs. For example, NACTEP funds must not be used to supplant Tribal and other non-Federal funds with Federal funds in order to pay the costs of students' tuition, dependent care, transportation, books, supplies, and other costs associated with participation in a CTE program.

Funds under NACTEP should not be used to replace Federal student financial aid. The Act does not authorize the Secretary to fund projects that serve primarily as entities through which students may apply for and receive tuition and other financial assistance.

(c) *Limitation on Services:* Section 315 of the Act prohibits the use of funds received under the Act to provide CTE programs to students prior to the seventh grade.

## IV. Application and Submission Information

1. *Address to Request Application Package:* Gwen Washington, U.S. Department of Education, 400 Maryland Avenue SW, Room 11076, Potomac Center Plaza, Washington, DC 20202–7241. Telephone: (202) 245–7790. Fax: (202) 245–7170. Or Linda Mayo, U.S. Department of Education, 400 Maryland Avenue SW, Room 11075, Potomac Center Plaza, Washington, DC 20202–7241. Telephone: (202) 245–7792. Fax: (202) 245–7170 or by email: [NACTEPgrant@ed.gov](mailto:NACTEPgrant@ed.gov).

You may also obtain an application package via the internet from the following address: [www.ed.gov/GrantApps/](http://www.ed.gov/GrantApps/).

If you use a TDD or a TTY, call the FRS, toll-free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the program contact persons listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

*Notice of Intent to Apply:* We will be able to develop a more efficient process for reviewing grant applications if we can anticipate the number of applicants

that intend to apply for funding under this competition. Therefore, we strongly encourage each potential applicant to notify us of the applicant's intent to submit an application for funding by sending a short email message. This short email should provide the applicant organization's name and address. Please send this email notification to [NACTEPgrant@ed.gov](mailto:NACTEPgrant@ed.gov) with "Intent to Apply" in the email subject line. Applicants that do not provide this email notification may still apply for funding.

### 3. Submission Dates and Times:

*Applications Available:* February 5, 2018.

*Deadline for Transmittal of Applications:* March 19, 2018.

A webinar for prospective applicants will be held for this competition shortly after this notice's publication date. The webinar is intended to provide technical assistance to all interested grant applicants. Information regarding the webinar can be found on the Perkins Collaborative Resource Network at <http://cte.ed.gov/>.

Applications for grants under this competition may be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the persons listed under **FOR FURTHER INFORMATION CONTACT**. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following website: <http://fedgov.dnb.com/webform>. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

**Note:** Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at [www.SAM.gov](http://www.SAM.gov). To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: <http://www2.ed.gov/fund/grant/apply/sam-faqs.html>.

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with

*Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* web page: [www.grants.gov/web/grants/register.html](http://www.grants.gov/web/grants/register.html).

### 7. Other Submission Requirements:

Applications for grants under this program may be submitted electronically or in paper format by mail or hand delivery.

#### a. Electronic Submission of Applications.

We are participating as a partner in the Governmentwide *Grants.gov* Apply site. NACTEP, CFDA number 84.101A, is included in this project. We request your participation in *Grants.gov*.

If you choose to submit your application electronically, you must use the Governmentwide *Grants.gov* Apply site at [www.Grants.gov](http://www.Grants.gov). You may not email an electronic copy of a grant application to us.

A *Grants.gov* applicant must apply online using Workspace, a shared environment where members of a grant team may simultaneously access and edit different webforms within an application. An applicant can create an individual Workspace for each application notice and, thus, establish for that application a collaborative application package that allows more than one person in the applicant's organization to work concurrently on an application. The applicant can, thus, assign other users to participate in the Workspace. The system also enables the applicant to reuse forms from previous submissions; check them in and out and complete them; and submit its application package. For access to complete instructions on how to apply, refer to: [www.grants.gov/web/grants/applicants/apply-for-grants.html](http://www.grants.gov/web/grants/applicants/apply-for-grants.html).

You may access the electronic grant application for NACTEP at [www.Grants.gov](http://www.Grants.gov). You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.101, not 84.101A).

Please note the following:

- Your participation in *Grants.gov* is voluntary. When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is

received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.

- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at [www.G5.gov](http://www.G5.gov). In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* website at [www.grants.gov/web/grants/applicants/apply-for-grants.html](http://www.grants.gov/web/grants/applicants/apply-for-grants.html).

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.

- If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- If you submit your application electronically, you must upload any narrative sections and all other attachments to your application as files in a read-only, flattened Portable Document Format (PDF), meaning any fillable PDF documents must be saved as flattened, nonfillable files. Therefore, do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, flattened PDF (e.g., Word, Excel, WordPerfect, etc.) or submit a password-protected file, we

will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF. There is no need to password protect a file in order to meet the requirement to submit a read-only, flattened PDF. And, as noted above, the Department will not review password-protected files.

- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, flattened PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System:* If you are experiencing problems submitting your application through *Grants.gov*, please

contact the *Grants.gov* Support Desk, toll-free, at 1-800-518-4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the persons listed under **FOR FURTHER INFORMATION CONTACT** and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

#### b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.101A), LBJ Basement Level 1, 400 Maryland Avenue SW, Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.

- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

- (3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.
- (2) A mail receipt that is not dated by the U.S. Postal Service.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

#### c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.101A, 550 12th Street SW, Room 7039, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

**Note:** Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

### V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from the Notice of Final Requirements, and are as follows.

The maximum score for each criterion is indicated in parentheses.

(a) *Need for project* (Up to 5 points). In determining the need for the proposed project, we consider the extent of the need for the services to be provided or the activities to be carried out by the proposed project, as evidenced by data on such phenomena as local labor market demand or

occupational trends, or from surveys, recommendations from accrediting agencies, or Tribal economic development plans.

(b) *Quality of the project design* (Up to 40 points). In determining the quality of the design of the proposed project, we consider the following factors:

(1) The extent to which the services to be provided by the proposed project will create opportunities for students to receive an industry-recognized credential; become employed in high skill, high-wage, and high-demand occupations; or both. (Up to 20 points).

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs, as evidenced by the applicant's description of programs and activities that align with the target population's needs. (Up to 10 points).

(3) The extent to which the proposed project will establish linkages with or will be coordinated with similar or related efforts, and with community, State, or Federal resources, where such opportunities and resources exist. (Up to 5 points).

(4) The extent to which the training or professional development services to be provided by the proposed project would be of sufficient quality, intensity, and duration to lead to improvements in practice among the project staff and instructors, including the extent to which the proposed training and professional development plans address ways in which learning gaps will be addressed and how continuous review of performance will be conducted to identify training needs. (Up to 5 points).

(c) *Adequacy of resources* (Up to 20 points). In determining the adequacy of resources for the proposed project, we consider the following factors:

(1) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization(s) and the Tribal entity or entities to be served. (Up to 5 points).

(2) The extent to which the budget is adequate and costs are reasonable in relation to the objectives of the proposed project. (Up to 5 points).

(3) The relevance and demonstrated commitment (e.g., through written CTE agreements, memoranda of understanding, letters of support and commitment, or commitments to employ project participants, as appropriate) of the applicant, members of the consortium, local employers, or Tribal entities to be served by the project. (Up to 5 points).

(4) The extent to which the project will use instructors who are certified to

teach in the field in which they will provide instruction. (Up to 5 points).

(d) *Quality of the management plan* (Up to 25 points). In determining the quality of the management plan for the proposed project, we consider the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and the milestones and performance standards for accomplishing project tasks. (Up to 10 points).

(2) The extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 5 points).

(3) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (Up to 5 points).

(4) The qualifications, including relevant training, expertise, and experience, of the project director, key personnel, and project consultants. (Up to 5 points).

(e) *Quality of the project evaluation* (Up to 10 points). In determining the quality of the evaluation, we consider the following factors:

(1) The extent to which the methods of evaluation proposed by the grantee are thorough, feasible, and include the use of objective performance measures that are clearly related to the intended outcomes of the project and the Government Performance and Results Act of 1993 (GPRA) performance measures. (Up to 5 points).

(2) The extent to which the methods of evaluation will provide performance feedback and continuous improvement toward achieving intended outcomes. (Up to 5 points).

2. *Additional Selection Factors:* In accordance with the requirement in section 116(e) of the Act, we have included the following additional selection factors and will award additional points to any application addressing the following factors, as indicated. These additional factors from the Notice of Final Requirements are as follows.

We will award—

(a) Up to 5 additional points to applications that propose exemplary approaches that involve, coordinate with, or encourage Tribal economic development plans; and

(b) Five points to applications from Tribally controlled colleges or universities that—

(1) Are accredited or are candidates for accreditation by a nationally recognized accreditation organization as an institution of postsecondary CTE; or

(2) Operate CTE programs that are accredited or are candidates for accreditation by a nationally recognized accreditation organization and issue certificates for completion of CTE programs (20 U.S.C. 2326(e)).

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal

Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

## VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirement:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license shall extend only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Please refer to the *Applicable Regulations* section to see if an exception under 2 CFR 3474 applies for this program. For additional information on the open licensing requirements please refer to 2 CFR 3474.20(c).

4. *Reporting:* (a) If you apply for a grant under this competition, you must

ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to [www.ed.gov/fund/grant/apply/appforms/appforms.html](http://www.ed.gov/fund/grant/apply/appforms/appforms.html).

5. *Performance Measures:* Pursuant to GPRA, the Department has established the following performance measures that it will use to evaluate the overall effectiveness of the grantee's project, as well as NACTEP as a whole:

(a) At the secondary level: An increase in the percentage of CTE students who—

(1) Attain academic proficiency, as demonstrated by meeting academic content standards and student academic achievement standards that meet challenging State-defined academic standards for reading/language arts and mathematics;

(2) Attain career and technical skill proficiencies, including student achievement on technical assessments that are aligned with industry-recognized standards;

(3) Attain a secondary school diploma;

(4) If a credential, certificate, or degree is offered by the State in which the project operates, in conjunction with a secondary school diploma, attain a proficiency credential, certificate, or degree in conjunction with a secondary school diploma; or

(5) Are placed in—

(i) Postsecondary education or advanced training;

(ii) Military service; or

(iii) Employment.

(b) At the postsecondary level: An increase in the percentage of CTE students who—

(1) Attain challenging career and technical skill proficiencies, including student achievement on technical assessments that are aligned with industry-recognized standards;

(2) Attain an industry-recognized credential, a certificate, or a degree;

(3) Are retained in postsecondary education or transfer to a baccalaureate degree program;

(4) Are placed in—

(i) Military service; or

(ii) Apprenticeship programs; or

(5) Are placed or have been retained in employment, including in high-skill, high-wage, or high-demand occupations or professions.

(c) At the adult education level: An increase in the percentage of participating adult career and technical education students who—

(1) Enroll in a postsecondary education or training program;

(2) Attain career and technical education skill proficiencies aligned with industry-recognized standards;

(3) Receive industry-recognized credentials or certificates; or

(4) Are placed in a job, upgraded in a job, or retain employment.

**Note:** All grantees will be expected to submit an annual performance report addressing these performance measures, to the extent feasible and to the extent that they apply to each grantee's NACTEP project.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

## VII. Other Information

**Accessible Format:** Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotope, or compact disc) on request to the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**. If you use a TDD or TTY, call the FRS, toll-free, at 1-800-877-8339.

**Electronic Access to This Document:** The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is

available via the Federal Digital System at: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 31, 2018.

**Michael E. Wooten,**

*Acting Assistant Secretary for Career, Technical, and Adult Education.*

[FR Doc. 2018-02246 Filed 2-2-18; 8:45 am]

**BILLING CODE 4000-01-P**

## DEPARTMENT OF EDUCATION

[Docket No.: ED-2017-ICCD-0145]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; SEA and LEA Self-Assessment and Monitoring Protocol

**AGENCY:** Office of Elementary and Secondary Education (OESE), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

**DATES:** Interested persons are invited to submit comments on or before March 7, 2018.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2017-ICCD-0145. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216-44, Washington, DC 20202-4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Patrick Carr, 202-708-8196.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* SEA and LEA Self-Assessment and Monitoring Protocol.

*OMB Control Number:* 1810-NEW.

*Type of Review:* A new information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 60.

*Total Estimated Number of Annual Burden Hours:* 16,800.

*Abstract:* OSS administrators Title I, Sections 1001-1004 (School Improvement); Title I, Part A (Improving Basic Programs Operated by Local Educational Agencies); Title I, Part B (Enhanced Assessments Grants (EAG), and Grants for State Assessments and Related Activities); Title II, Part A (Supporting Effective Instruction); Title III, Part A (English Language Acquisition, Language Enhancement, and Academic Achievement); and School Improvement Grants (SIG). Annual fiscal reviews—annual phone or on-site conversations with a purposeful sample of SEA and LEA program directors and coordinators—help ensure

that an SEA and its LEAs are making progress toward improving student achievement and the quality of instruction for all students and are ensuring requirements are met through the review of fiscal requirements to safeguard public funds from waste, fraud, and abuse. The information shared with the OSS also informs the selection and delivery of technical assistance to SEAs and aligns structures, processes, and routines so the OSS can regularly monitor the connection between grant administration and intended outcomes. Because grantees are monitored on a multiyear cycle, administration of this information collection, including the publication of fiscal review results, is necessary to enable the OSS to identify potential areas of noncompliance ahead of formal monitoring visits, decreasing the need for enforcement actions and minimizing burden for SEAs.

Dated: January 31, 2018.

**Tomakie Washington,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018-02259 Filed 2-2-18; 8:45 am]

BILLING CODE 4000-01-P

## DEPARTMENT OF EDUCATION

### Tests Determined To Be Suitable for Use in the National Reporting System for Adult Education

**AGENCY:** Office of Career, Technical, and Adult Education, Department of Education.

**ACTION:** Notice.

**SUMMARY:** The Secretary announces tests, test forms, and delivery formats that the Secretary determines to be suitable for use in the National Reporting System for Adult Education (NRS).

**FOR FURTHER INFORMATION CONTACT:** Jay LeMaster, Department of Education, 400 Maryland Avenue SW, Room 11-152, Potomac Center Plaza, Washington, DC 20202-7240. Telephone: (202) 245-6218 or by email: [John.LeMaster@ed.gov](mailto:John.LeMaster@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1-800-877-8339.

**SUPPLEMENTARY INFORMATION:** On January 14, 2008, we published in the **Federal Register** final regulations for 34 CFR part 462, Measuring Educational Gain in the National Reporting System for Adult Education (NRS regulations) (73 FR 2306). The NRS regulations

established the process the Secretary uses to determine the suitability of tests for use in the NRS by States and local eligible providers. We annually publish in the **Federal Register** and post on the internet at [www.nrsweb.org](http://www.nrsweb.org) a list of the names of tests and the educational functioning levels the tests are suitable to measure in the NRS as required by § 462.12(c)(2).

On December 13, 2016, the Secretary published in the **Federal Register** (81 FR 89920) an annual notice of tests determined to be suitable for use in the NRS (December 2016 notice). In the December 2016 notice, the Secretary extended the approved periods for all 12 of the tests listed in the notice through February 2, 2019.

On September 7, 2017, the Secretary published in the **Federal Register** (82 FR 42339) an annual notice of tests determined to be suitable for use in the NRS (September 2017 notice). In the September 2017 notice, the Secretary announced a new test and test forms that were determined to be suitable for use in the NRS, in accordance with § 462.13.

In addition to the tests identified in the December 2016 and September 2017 notices as determined to be suitable for use in the NRS through February 2, 2019, and September 7, 2024, respectively, the Secretary now announces another test and test forms that have been determined to be suitable for use in the NRS, in accordance with § 462.13. This test measures the NRS educational functioning levels for Literacy/English Language Arts at all Adult Basic Education (ABE) levels, as described in Appendix A of *Measures and Methods for the National Reporting System for Adult Education* (OMB Control Number: 1830-0027).

#### Approved Tests, Forms, and Approved Periods

Adult education programs must use only the approved forms and computer-based delivery formats for the tests published in this document. If a particular test form or computer delivery format is not explicitly specified for a test in the December 2016 notice, the September 2017 notice, or in this notice, it is not approved for use in the NRS.

#### Test Determined To Be Suitable for Use in the NRS for a Seven-Year Period From the Date of Publication of This Notice

The Secretary has determined that the following test is suitable for use in Literacy/English Language Arts at all ABE levels of the NRS for a period of

seven years from the date of publication of this notice:

*Comprehensive Adult Student Assessment System (CASAS) Reading GOALS Series.* Forms 901, 902, 903, 904, 905, 906, 907, and 908 are approved for use on paper and through a computer-based delivery format. Publisher: CASAS, 5151 Murphy Canyon Road, Suite 220, San Diego, CA 92123-4339. Telephone: (800) 255-1036. Internet: [www.casas.org/](http://www.casas.org/).

#### Revocation of Tests

Under certain circumstances, the Secretary may revoke the determination that a test is suitable (see § 462.12(e)). If the Secretary revokes the determination of suitability, the Secretary announces through the **Federal Register** and posts on the internet at [www.nrsweb.org](http://www.nrsweb.org) a notice of that revocation, along with the date by which States and local eligible providers must stop using the revoked test.

**Accessible Format:** Individuals with disabilities can obtain this document in an accessible format (such as braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

**Electronic Access to This Document:** The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

**Program Authority:** 29 U.S.C. 3292.

Dated: January 31, 2018.

**Michael E. Wooten,**

*Acting Assistant Secretary for Career, Technical, and Adult Education.*

[FR Doc. 2018-02237 Filed 2-2-18; 8:45 am]

BILLING CODE 4000-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10–3099–018.  
*Applicants:* RC Cape May Holdings, LLC.

*Description:* Second Supplement to June 30, 2017 Triennial Market-Based Rate Update Filing for the Northeast Region of RC Cape May Holdings, LLC.  
*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5105.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER12–1266–008.

*Applicants:* Midcontinent

Independent System Operator, Inc.

*Description:* Compliance filing: 2018–01–26 Order 745 Amended Compliance Filing to be effective 6/12/2012.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5101.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER17–481–004.

*Applicants:* CPV Maryland, LLC.

*Description:* Compliance filing: Compliance Filing of Reactive Power Rate Schedule in ER17–481 and EL17–39 to be effective 2/1/2017.

*Filed Date:* 1/25/18.

*Accession Number:* 20180125–5137.  
*Comments Due:* 5 p.m. ET 2/15/18.

*Docket Numbers:* ER17–1191–004.

*Applicants:* Otter Tail Power

Company.

*Description:* Compliance filing: Compliance of Executed Rate Schedule No. 151 with Minnkota to be effective 5/15/2017.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5152.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER17–1666–002.

*Applicants:* Red Pine Wind Project, LLC.

*Description:* Notice of Non-Material Change in Status of Red Pine Wind Project, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5068.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER17–2085–001.

*Applicants:* Alliant Energy Corporate Services, Inc.

*Description:* Compliance filing: AECS Reactive Power Compliance Filing to be effective 9/1/2017.

*Filed Date:* 1/25/18.

*Accession Number:* 20180125–5162.  
*Comments Due:* 5 p.m. ET 2/15/18.

*Docket Numbers:* ER17–2258–001.

*Applicants:* Rock Falls Wind Farm LLC.

*Description:* Notice of Non-Material Change in Status of Rock Falls Wind Farm LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5062.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER17–2409–001.

*Applicants:* Alliant Energy Corporate Services, Inc.

*Description:* Compliance filing: AECS Reactive Power Compliance Filing to be effective 11/1/2017.

*Filed Date:* 1/25/18.

*Accession Number:* 20180125–5163.  
*Comments Due:* 5 p.m. ET 2/15/18.

*Docket Numbers:* ER18–152–001.

*Applicants:* Otter Tail Power Company.

*Description:* Compliance filing: Compliance Filing of Executed Coyote 1 Station Transmission Facilities Agreement to be effective 12/24/2017.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5167.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–716–000.

*Applicants:* New England Power Company.

*Description:* Tariff Cancellation: Notice of Cancellation of Rate Schedule No. 484 to be effective 3/28/2018.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5006.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–717–000.

*Applicants:* Commonwealth Edison Company, PJM Interconnection, L.L.C., Midwest Generation, LLC.

*Description:* Compliance filing: ComEd submits Notice of Termination of IA, Service Agreement No. 1064 to be effective N/A.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5050.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–718–000.

*Applicants:* Guzman Energy Partners LLC.

*Description:* § 205(d) Rate Filing: Market-Based Rate Tariff #1

Amendment to be effective 10/4/2017.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5079.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–719–000.

*Applicants:* National Grid Generation LLC.

*Description:* § 205(d) Rate Filing: A&R PSA Amendment No. 3 to be effective 4/1/2018.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5099.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–720–000.

*Applicants:* Sierra Pacific Power Company.

*Description:* Tariff Cancellation: Rate Schedule No. 27—SPPC/BPA GTA Cancellation to be effective 1/27/2018.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5103.  
*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–721–000.

*Applicants:* ITC Midwest LLC.

*Description:* § 205(d) Rate Filing: Filing of a Master JUA for Distribution Underbuild with T.I.P. REC to be effective 3/27/2018.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5120.  
*Comments Due:* 5 p.m. ET 2/16/18.

Take notice that the Commission received the following public utility holding company filings:

*Docket Numbers:* PH18–4–000.

*Applicants:* Spire Inc.

*Description:* Spire Inc. submits FERC 65–A Notice of Material Change in Fact of Exemption Notification.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5162.  
*Comments Due:* 5 p.m. ET 2/16/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 26, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–02224 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717-01-P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG18–33–000.

*Applicants:* Gregory Power Partners LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Gregory Power Partners LLC.

*Filed Date:* 1/26/18.  
*Accession Number:* 20180126–5190.  
*Comments Due:* 5 p.m. ET 2/16/18.  
*Docket Numbers:* EG18–34–000.  
*Applicants:* Montpelier Generating Station, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Montpelier Generating Station, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5191.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* EG18–35–000.

*Applicants:* Monument Generating Station, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Monument Generating Station, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5197.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* EG18–36–000.

*Applicants:* O.H. Hutchings CT, LLC.  
*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of O.H. Hutchings CT, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5198.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* EG18–37–000.

*Applicants:* Sidney, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Sidney, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5201.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* EG18–38–000.

*Applicants:* Tait Electric Generating Station, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Tait Electric Generating Station, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5203.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* EG18–39–000.

*Applicants:* Yankee Street, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Yankee Street, LLC.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5204.

*Comments Due:* 5 p.m. ET 2/16/18.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10–2331–069; ER10–2317–059; ER13–1351–041.

*Applicants:* J.P. Morgan Ventures Energy Corporation, BE CA LLC, Florida Power Development LLC.

*Description:* Notice of Non-Material Change in Status of the J.P. Morgan Sellers.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5056.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER10–2331–070;

ER10–2317–060; ER13–1351–042.

*Applicants:* J.P. Morgan Ventures Energy Corporation, BE CA LLC, Florida Power Development LLC.

*Description:* Notice of Non-Material Change in Status of the J.P. Morgan Sellers.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5060.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER10–2674–012;

ER15–1596–006; ER15–1598–005;

ER15–1599–006; ER14–1569–007;

ER15–1600–004; ER15–1602–004;

ER10–2619–009; ER15–1603–004;

ER10–2616–013; ER15–1605–004;

ER11–4400–010; ER15–1958–005;

ER15–1606–004; ER15–1607–004;

ER15–1608–004; ER10–1547–012;

ER14–883–008; ER13–2475–010; ER12–

192–013; ER10–1550–013; ER10–1975–

021; ER10–2617–008; ER10–2677–012;

ER11–4266–014.

*Applicants:* Calumet Energy Team, LLC, Dynegy Commercial Asset Management, LLC, Dynegy Dicks Creek, LLC, Dynegy Energy Services (East), LLC, Dynegy Energy Services, LLC, Dynegy Fayette II, LLC, Dynegy Hanging Rock II, LLC, Dynegy Kendall Energy, LLC, Dynegy Killen, LLC, Dynegy Marketing and Trade, LLC, Dynegy Miami Fort, LLC, Dynegy Power Marketing, LLC, Dynegy Resources Management, LLC, Dynegy Stuart, LLC, Dynegy Washington II, LLC, Dynegy Zimmer, LLC, Hopewell Cogeneration Limited Partnership, Illinois Power Marketing Company, Kincaid Generation, L.L.C., Liberty Electric Power, LLC, Northeastern Power Company, North Jersey Energy Associates, A Limited Partnership, Ontelaunee Power Operating Company, LLC, Pleasants Energy, LLC, Richland-Stryker Generation LLC.

*Description:* Notification of Change in Status of the Dynegy PJM MBR Sellers.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5232.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER10–2984–039.

*Applicants:* Merrill Lynch Commodities, Inc.

*Description:* Notice of Non-Material Change in Status of Merrill Lynch Commodities, Inc.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5228.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER10–2984–040.

*Applicants:* Merrill Lynch Commodities, Inc.

*Description:* Notice of Non-Material Change in Status of Merrill Lynch Commodities, Inc.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5233.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–152–002.

*Applicants:* Otter Tail Power Company.

*Description:* Compliance filing: Corrected Compliance Filing of Executed Coyote 1 Agreement to be effective 12/24/2017.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126–5213.

*Comments Due:* 5 p.m. ET 2/16/18.

*Docket Numbers:* ER18–318–001.

*Applicants:* Virginia Electric and Power Company, PJM Interconnection, L.L.C.

*Description:* Compliance filing: Dominion submits Revisions to Attachment H–16A in ER18–318–000 to be effective 10/19/2017.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5099.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–378–001.

*Applicants:* Public Service Company of Colorado.

*Description:* Tariff Amendment: 1/29/2018 Deferral to IREA PPA to be effective 12/31/9998.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5117.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–622–001.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* Compliance filing: 2018–01–29 Amendment to Order 831 Energy Offer Cap Compliance to be effective 11/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5248.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–722–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Original WMPA SA No. 4910; Queue No. AC2–161 to be effective 1/5/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5175.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–723–000.

*Applicants:* American Transmission Systems, Incorporation, PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: ATSI submits ECSA, Service Agreement No. 4864 with Toledo Edison Company to be effective 4/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5185.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–724–000.

*Applicants:* Grid Power Direct, LLC.  
*Description:* Baseline eTariff Filing: Grid Power Direct MBR Application to be effective 3/31/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5220.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–725–000.

*Applicants:* Public Service Company of New Mexico.

*Description:* § 205(d) Rate Filing: Modifications to NITSA/NOA between PNM and Tri-State to be effective 1/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5249.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–726–000.

*Applicants:* Public Service Company of New Mexico.

*Description:* § 205(d) Rate Filing: Modification to Contract P0695 between PNM and Western to be effective 1/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129–5293.

*Comments Due:* 5 p.m. ET 2/20/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 29, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–02225 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Commissioner and Staff Attendance at North American Electric Reliability Corporation Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission

and/or Commission staff may attend the following meetings:

North American Electric Reliability Corporation, Member Representatives Committee and Board of Trustees Meetings, Board of Trustees Corporate Governance and Human Resources Committee, Finance and Audit Committee, Compliance Committee, and Standards Oversight and Technology Committee Meetings  
Hilton Fort Lauderdale Marina, 1881 SE 17th Street, Fort Lauderdale, FL 33316

February 7 (8:00 a.m.–5:00 p.m. eastern time) and February 8 (8:30 a.m.–12:00 p.m. eastern time), 2018

Further information regarding these meetings may be found at: <http://www.nerc.com/Pages/Calendar.aspx>.

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. RR17–6, North American Electric Reliability Corporation

For further information, please contact Jonathan First, 202–502–8529, or [jonathan.first@ferc.gov](mailto:jonathan.first@ferc.gov).

Dated: January 30, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–02240 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 3932–011]

#### Hydrodyne Industries, LLC; Hydrodyne Energy, LLC; Notice of Transfer of Exemption

1. By letter filed January 17, 2018, George S. Cook, Manager, Hydrodyne Industries, LLC, exemptee and Michael Rickly P.E., Manager, Hydrodyne Energy, LLC informed the Commission that the exemption from licensing for the Little River Hydroelectric Project No. 3932, originally issued May 4, 1982<sup>1</sup> has been transferred to Hydrodyne Energy, LLC. The project is located on the Little River in Montgomery County, North Carolina. The transfer of an exemption does not require Commission approval.

2. Hydrodyne Energy, LLC is now the exemptee of the Little River Hydroelectric Project No. 3932. All

<sup>1</sup> Order Granting Exemption From Licensing of a Small Hydroelectric Project of 5 Megawatts or Less. *American Hydro Power Company*, 19 FERC ¶ 62,191 (1982).

correspondence should be forwarded to: Mr. Michael Rickly P.E., Manager, Hydrodyne Energy, LLC, 1700 Joyce Ave., Columbus, OH 43219, Phone: 614–297–9877, Cell: 614–648–2466, Fax: 614–297–9878, Email: [mike@rickly.com](mailto:mike@rickly.com).

Dated: January 30, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–02241 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2530–054]

#### Brookfield White Pine Hydro LLC; Notice of Intent To File License Application, Filing of Pre-Application Document (PAD), Commencement of Pre-Filing Process, and Scoping; Request for Comments on the PAD and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Process.

b. *Project No.:* 2530–054.

c. *Dated Filed:* November 30, 2017.

d. *Submitted By:* Brookfield White Pine Hydro LLC (White Pine Hydro).

e. *Name of Project:* Hiram Hydroelectric Project.

f. *Location:* On the Saco River in the towns of Hiram, Baldwin, Brownfield, and Denmark, within Oxford and Cumberland Counties, Maine. The project does not occupy United States lands.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's Regulations.

h. *Potential Applicant Contact:* Frank Dunlap, Licensing Specialist, Brookfield Renewable, Brookfield White Pine Hydro LLC, 150 Maine Street, Lewiston, Maine 04240; (207) 755–5603; [frank.dunlap@brookfieldrenewable.com](mailto:frank.dunlap@brookfieldrenewable.com).

i. *FERC Contact:* Allan Creamer at (202) 502–8365, or email at [allan.creamer@ferc.gov](mailto:allan.creamer@ferc.gov).

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in

the preparation of the environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (1) The U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and (2) the State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating White Pine Hydro as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. White Pine Hydro filed with the Commission a Pre-Application Document (PAD; including a proposed process plan and schedule), pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's website (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at [FERCONlineSupport@ferc.gov](mailto:FERCONlineSupport@ferc.gov), or toll free at 1-866-208-3676, or for TTY, (202) 502-8659. A copy is also available for inspection and reproduction at the address in paragraph h.

Register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. With this notice, we are soliciting comments on the PAD and Commission staff's Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, as well as study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission. Documents may be filed electronically via the internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website <http://www.ferc.gov/docs-filing/efiling.asp>.

Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, send a paper copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

All filings with the Commission must include on the first page, the project name (Hiram Hydroelectric Project and number P-2530-054), and bear the appropriate heading: "Comments on Pre-Application Document," "Study Requests," "Comments on Scoping Document 1," "Request for Cooperating Agency Status," or "Communications to and from Commission Staff." Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by March 30, 2018.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, the meetings listed below will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

#### Scoping Meetings

Commission staff will hold two scoping meetings in the vicinity of the project at the time and place noted below. The daytime meeting will focus on resource agency, Indian tribes, and non-governmental organization concerns, while the evening meeting is primarily for receiving input from the public. We invite all interested agencies, Indian tribes, organizations, and individuals to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. The times and locations of these meetings are as follows:

##### Evening Scoping Meeting

*Date:* Wednesday, February 28, 2018.

*Time:* 6:30 p.m.

*Location:* Baldwin Community Center, Conference Room, 534 Pequawket Trail, ME 113, West Baldwin, ME 04091.

*Phone:* Danielle Taylor at (207) 625-9107.

##### Daytime Scoping Meeting

*Date:* Thursday, March 1, 2018.

*Time:* 9:00 a.m.

*Location:* Brookfield Renewable Offices, Moosehead Room, 150 Main Street, Lewiston, ME 04240.

*Phone:* Frank Dunlap at (207) 755-5603.

SD1, which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 will be available at the scoping meetings, or may be viewed on the web at <http://www.ferc.gov> using the "eLibrary" link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

#### Environmental Site Review

The potential applicant and Commission staff will conduct an Environmental Site Review of the project on Thursday, March 1, 2018, starting at 2:00 p.m. All participants should meet at White Pine Hydro's Hiram Dam, located at 45 Hiram Dam Road, Baldwin, ME 04091. All participants are responsible for their own transportation. Anyone with questions about the site visit should contact Mr. Frank Dunlap of White Pine Hydro at (207) 755-5603 on or before February 20, 2018.

#### Meeting Objectives

At the scoping meetings, staff will: (1) Initiate scoping of the issues; (2) review and discuss existing conditions and resource management objectives; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in Part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of federal, state, and tribal permitting and certification processes; and (5) discuss the appropriateness of any federal or state agency or Indian tribe acting as a cooperating agency for development of an environmental document.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and SD1 are included in item n. of this notice.

**Meeting Procedures**

The meetings will be recorded by a stenographer. The transcripts will be placed in the public record for the project.

Dated: January 29, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018-02229 Filed 2-2-18; 8:45 am]

**BILLING CODE 6717-01-P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****Combined Notice of Filings**

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

**Filings Instituting Proceedings**

*Docket Numbers:* RP11-1711-000.

*Applicants:* Texas Gas Transmission, LLC.

*Description:* Report Filing: 2017 Cash Out Filing.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5075.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP13-886-003.

*Applicants:* Southern Natural Gas Company, L.L.C.

*Description:* Compliance filing Petition to Amend Stipulation and Agreement under RP13-886.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5286.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP17-197-008.

*Applicants:* Dominion Energy Cove Point LNG, LP.

*Description:* Compliance filing DECP—RP17-197 Settlement Compliance—Appendix D to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5076.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-365-000.

*Applicants:* Nautilus Pipeline Company, L.L.C.

*Description:* § 4(d) Rate Filing: Nautilus Section-Based Baseline Tariff to be effective 3/15/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5063.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-366-000.

*Applicants:* Algonquin Gas Transmission, LLC.

*Description:* § 4(d) Rate Filing: Negotiated Rates—Bay State Releases eff 2-1-2018 to be effective 2/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5067.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-367-000.

*Applicants:* Kinder Morgan Illinois Pipeline LLC.

*Description:* Penalty Revenue Crediting Report of Kinder Morgan Illinois Pipeline LLC.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5068.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-368-000.

*Applicants:* Columbia Gulf Transmission, LLC.

*Description:* Compliance filing Cameron Access Rate Implementation Compliance CP15-109 to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5070.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-369-000.

*Applicants:* Sea Robin Pipeline Company, LLC.

*Description:* § 4(d) Rate Filing: Revise Quality Provisions to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5071.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-370-000.

*Applicants:* Kinder Morgan Illinois Pipeline LLC.

*Description:* § 4(d) Rate Filing: Removal of Negotiated Rate Agreement to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5087.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-371-000.

*Applicants:* Kinder Morgan Louisiana Pipeline LLC.

*Description:* Penalty Revenue Crediting Report of Kinder Morgan Louisiana Pipeline LLC.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5137.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-372-000.

*Applicants:* El Paso Natural Gas Company, L.L.C.

*Description:* § 4(d) Rate Filing: Transportation Service Agreement Update Filing (City of Mesa) to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5252.

*Comments Due:* 5 p.m. ET 2/12/18.

*Docket Numbers:* RP18-373-000.

*Applicants:* Wyoming Interstate Company, L.L.C.

*Description:* § 4(d) Rate Filing: Fuel and L&U Update to be effective 3/1/2018.

*Filed Date:* 1/29/18.

*Accession Number:* 20180129-5253.

*Comments Due:* 5 p.m. ET 2/12/18.

The filings are accessible in the Commission's eLibrary system by

clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 30, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018-02243 Filed 2-2-18; 8:45 am]

**BILLING CODE 6717-01-P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10-2759-007; ER10-2732-014; ER10-2733-014; ER10-2734-014; ER10-2736-014; ER10-2737-014; ER10-2741-014; ER10-2749-014; ER10-2752-014; ER12-2492-010; ER12-2493-010; ER12-2494-010; ER12-2495-010; ER12-2496-010; ER16-2455-004; ER16-2456-004; ER16-2457-004; ER16-2458-004; ER16-2459-004; ER14-264-004; ER10-2631-007; ER10-1437-007; ER13-815-005.

*Applicants:* Bridgeport Energy LLC, Emera Energy Services Inc., Emera Energy U.S. Subsidiary No. 1, Inc., Emera Energy U.S. Subsidiary No. 2, Inc., Emera Energy Services Subsidiary No. 1 LLC, Emera Energy Services Subsidiary No. 2 LLC, Emera Energy Services Subsidiary No. 3 LLC, Emera Energy Services Subsidiary No. 4 LLC, Emera Energy Services Subsidiary No. 5 LLC, Emera Energy Services Subsidiary No. 6 LLC, Emera Energy Services Subsidiary No. 7 LLC, Emera Energy Services Subsidiary No. 8 LLC, Emera Energy Services Subsidiary No. 9 LLC, Emera Energy Services Subsidiary No. 10 LLC, Emera Energy Services Subsidiary No. 11 LLC, Emera Energy Services Subsidiary No. 12 LLC, Emera Energy Services Subsidiary No. 13 LLC,

- Emera Energy Services Subsidiary No. 14 LLC, Emera Energy Services Subsidiary No. 15 LLC, Emera Maine, Rumford Power Inc., Tampa Electric Company, Tiverton Power LLC.  
*Description:* Notice of Change in Status of the Emera Entities.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5224.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER10-2984-041.  
*Applicants:* Merrill Lynch Commodities, Inc.  
*Description:* Notice of Non-Material Change in Status of Merrill Lynch Commodities, Inc.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5347.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-136-002.  
*Applicants:* Midcontinent Independent System Operator, Inc.  
*Description:* Tariff Amendment: 2018-01-29 Deficiency Response re Rev to MISO-PJM JOA for congestion overlap to be effective 12/31/9998.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5344.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-137-002.  
*Applicants:* PJM Interconnection, L.L.C.  
*Description:* Tariff Amendment: Response to Deficiency Letter Issued December 28, 2017 in Docket No. ER18-137 to be effective 12/31/9998.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5345.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-727-000.  
*Applicants:* Southwest Power Pool, Inc.  
*Description:* § 205(d) Rate Filing: Tariff Revisions to Reflect Merger of ETEC and Tex-La to be effective 4/1/2018.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5310.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-728-000.  
*Applicants:* California Independent System Operator Corporation.  
*Description:* § 205(d) Rate Filing: 2018-01-29 Resource Adequacy Availability Incentive Mechanism Amendment to be effective 4/1/2018.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5336.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-729-000.  
*Applicants:* Entergy Mississippi, Inc.  
*Description:* Notice of Cancellation of Attala Interconnection and Service Charge Agreement of Entergy Mississippi, Inc.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5350.
- Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-730-000.  
*Applicants:* Linden VFT, LLC.  
*Description:* Application for Amendment of Existing Authority to Make Sales of Transmission Rights at Negotiated Rates of Linden VFT, LLC.  
*Filed Date:* 1/29/18.  
*Accession Number:* 20180129-5356.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-731-000.  
*Applicants:* Midcontinent Independent System Operator, Inc.  
*Description:* § 205(d) Rate Filing: 2018-01-30 Annual Schedule 31 Update to be effective 4/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5093.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-732-000.  
*Applicants:* Entergy Louisiana, LLC.  
*Description:* Notice of Cancellation of Perryville Interconnection and Service Charge Agreement of Entergy Louisiana, Inc.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5122.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-733-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: City of Evergreen NITSA Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5130.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-734-000.  
*Applicants:* Frenchtown III Solar, LLC.  
*Description:* Baseline eTariff Filing: Frenchtown III Reactive Service Filing to be effective 4/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5132.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-735-000.  
*Applicants:* Alabama Power Company.  
*Description:* Tariff Cancellation: SWE (Evergreen) NITSA Termination Filing to be effective 12/31/2017.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5133.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-736-000.  
*Applicants:* Southwest Power Pool, Inc.  
*Description:* § 205(d) Rate Filing: Revisions to Update Attachment AF—Frequently Constrained Areas to be effective 4/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5134.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-737-000.  
*Applicants:* Alabama Power Company.
- Description:* § 205(d) Rate Filing: City of Hartford NITSA Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5136.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-738-000.  
*Applicants:* Alabama Power Company.  
*Description:* Tariff Cancellation: SWE (Hartford) NITSA Termination Filing to be effective 12/31/2017.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5139.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-739-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: City of Robertsdale NITSA Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5140.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-740-000.  
*Applicants:* Alabama Power Company.  
*Description:* Tariff Cancellation: SWE (Robertsdale) NITSA Termination Filing to be effective 12/31/2017.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5141.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-741-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: SWE (Black Warrior) NITSA Rollover Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5143.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-742-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: SWE (Tombigbee) NITSA Rollover Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5144.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-743-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: City of Troy NITSA and NOA Filing to be effective 1/1/2018.  
*Filed Date:* 1/30/18.  
*Accession Number:* 20180130-5146.  
*Comments Due:* 5 p.m. ET 2/20/18.  
*Docket Numbers:* ER18-744-000.  
*Applicants:* Alabama Power Company.  
*Description:* § 205(d) Rate Filing: PowerSouth NITSA Amendments Filing (Add Wallsboro and Park Crossing DPs) to be effective 1/1/2018.

*Filed Date:* 1/30/18.

*Accession Number:* 20180130–5147.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–745–000.

*Applicants:* ISO New England Inc., Eversource Energy Service Company.

*Description:* § 205(d) Rate Filing: ISO–NE and Eversource—Original Service Agreement .0Under Schedule 21–ES to be effective 1/1/2018.

*Filed Date:* 1/30/18.

*Accession Number:* 20180130–5165.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–746–000.

*Applicants:* Northern Indiana Public Service Company.

*Description:* § 205(d) Rate Filing: WVPA IA, Recloser Replacements CIAC (2018) to be effective 1/31/2018.

*Filed Date:* 1/30/18.

*Accession Number:* 20180130–5178.

*Comments Due:* 5 p.m. ET 2/20/18.

*Docket Numbers:* ER18–747–000.

*Applicants:* Imperial Valley Solar 3, LLC.

*Description:* Baseline eTariff Filing: Imperial Valley Solar 3, LLC Co Tenancy Agreement to be effective 1/31/2018.

*Filed Date:* 1/30/18.

*Accession Number:* 20180130–5181.

*Comments Due:* 5 p.m. ET 2/20/18.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES18–22–000.

*Applicants:* AEP Texas Inc.

*Description:* Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of AEP Texas Inc.

*Filed Date:* 1/30/18.

*Accession Number:* 20180130–5253.

*Comments Due:* 5 p.m. ET 2/20/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 30, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–02226 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. EL18–58–000]

#### Oklahoma Municipal Power Authority v. Oklahoma Gas and Electric Company; Notice of Complaint

Take notice that on January 26, 2018, pursuant to section 206 and 306 of the Federal Power Act, 16 U.S.C. 824e, 825e, and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, .212, the Oklahoma Municipal Power Authority (Complainant) filed a formal complaint against Oklahoma Gas and Electric Company (Respondent) alleging that the formula rate used by Respondent to determine the charges for transmission service in Zone 7 of the Southwest Power Pool is unjust and unreasonable, all as more fully explained in the complaint.

Complainant certifies that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for

review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5:00 p.m. Eastern Time on February 15, 2018.

Dated: January 29, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018–02228 Filed 2–2–18; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 14865–000]

#### Watterra Energy, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On November 29, 2017, Watterra Energy, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Sutton Dam Hydroelectric Project to be located at the U.S. Army Corps of Engineers' (Corps) Sutton Dam, on the Elk River, in Sutton, Braxton County, West Virginia. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A new 70-foot-long, 55-foot-wide powerhouse containing three turbine-generator units with a total rated capacity of 14 megawatts; (2) a new multiple-port intake structure to be located at the upstream face of the Sutton dam; (3) a new 300-foot-long, 15-foot-diameter steel penstock; (4) a new 50-foot-long, 50-foot-wide switchyard; (5) a new 13.8-kilovolt, 500-foot-long transmission line; and (6) appurtenant facilities. The proposed project would have an annual generation of 47,200 megawatt-hours.

*Applicant Contact:* Craig Dalton, Watterra Energy, LLC, 220 West Main

Street, Hamilton, MT 59840; phone: 406-384-0080.

*FERC Contact:* Monir Chowdhury; phone: (202) 502-6736.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-14865-000.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-14865) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 30, 2018.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2018-02242 Filed 2-2-18; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 10532-006]

#### Water Facilities Authority a Joint Power Agency; Notice of Application for Surrender of Exemption, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Application for surrender of conduit exemption.

b. *Project No.:* 10532-006.

c. *Date Filed:* January 18, 2018.

d. *Licensee:* Water Facilities Authority a Joint Power Agency (WFA-JPA).

e. *Name of Project:* WFA-JPA Regional Water Supply Energy Recovery Facilities Project.

f. *Location:* The project is located on a water transmission pipeline near the City of Ontario, San Bernardino, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Licensee Contact:* Ms. Chelsea Murphy, Natural Resources Project Manager, SWCA Environmental Consultants, 150 South Arroyo Parkway, Second Floor, Pasadena, California, Telephone: (626) 240-0587 ext. 6609, [cmurphy@swca.com](mailto:cmurphy@swca.com).

i. *FERC Contact:* Ms. Rebecca Martin, (202) 502-6012, [Rebecca.Martin@ferc.gov](mailto:Rebecca.Martin@ferc.gov).

j. Deadline for filing comments, interventions, and protests is February 28, 2018. The Commission strongly encourages electronic filing. Please file motions to intervene, protests and comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-10532-006.

k. *Description of Request:* The project consists of the existing water supply transmission system and one powerhouse containing one turbine generating unit with a total rated capacity of 225 kilowatts (kW). The project has not operated since October 7, 2005. The demand for water at the project has been around 0.5 million gallons per day (MGD). The minimum required flow required to operate the hydrogenerator is 6.1 MGD. As a result, the exemptee, has determined it would like to surrender the exemption. Electricity to the hydrogenerator has been permanently disconnected. No ground disturbance is associated with the proposed surrender and project features will remain in place.

l. This filing may be viewed on the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>.

Enter the docket number (P-10532-006) excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. A copy is also available for inspection and reproduction in the Commission's Public Reference Room located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502-8371.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .212 and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to the surrender application that is the subject of this notice. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they

must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: January 29, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018-02230 Filed 2-2-18; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER18-724-000]

#### Grid Power Direct, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Grid Power Direct, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 20, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies

of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 30, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018-02239 Filed 2-2-18; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

#### Filings Instituting Proceedings

*Docket Numbers:* RP18-360-000.  
*Applicants:* Transcontinental Gas Pipe Line Company.  
*Description:* § 4(d) Rate Filing: DPEs—New York Bay to be effective 2/25/2018.  
*Filed Date:* 1/25/18.

*Accession Number:* 20180125-5042.  
*Comments Due:* 5 p.m. ET 2/6/18.

*Docket Numbers:* RP18-361-000.  
*Applicants:* Big Sandy Pipeline, LLC.  
*Description:* Compliance filing Big Sandy Fuel Filing Effective 3-1-2018.  
*Filed Date:* 1/25/18.

*Accession Number:* 20180125-5045.  
*Comments Due:* 5 p.m. ET 2/6/18.

*Docket Numbers:* RP18-362-000.  
*Applicants:* Southern LNG Company, L.L.C.

*Description:* § 4(d) Rate Filing: Dredging Surcharge Cost Adjustment—2018 to be effective 3/1/2018.  
*Filed Date:* 1/25/18.

*Accession Number:* 20180125-5112.  
*Comments Due:* 5 p.m. ET 2/6/18.

*Docket Numbers:* RP18-363-000.  
*Applicants:* Transcontinental Gas Pipe Line Company.

*Description:* § 4(d) Rate Filing: Rate Schedule S-2 Tracker effective 02-01-18 to be effective 2/1/2018.

*Filed Date:* 1/25/18.

*Accession Number:* 20180125-5164.

*Comments Due:* 5 p.m. ET 2/6/18.

*Docket Numbers:* RP18-364-000.

*Applicants:* Stagecoach Pipeline & Storage Company LLC.

*Description:* § 4(d) Rate Filing: Stagecoach Pipeline & Storage Company LLC—Filing of Tariff Changes to be effective 3/1/2018.

*Filed Date:* 1/26/18.

*Accession Number:* 20180126-5078.

*Comments Due:* 5 p.m. ET 2/7/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 29, 2018.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2018-02227 Filed 2-2-18; 8:45 am]

BILLING CODE 6717-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 17-22; DA 18-13]

### Termination of Dormant Proceedings

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of availability.

**SUMMARY:** In this document, the Consumer and Governmental Affairs Bureau announces the availability of the FCC order terminating, as dormant, certain docketed Commission proceedings.

**DATES:** The dockets are terminated as of February 5, 2018.

**FOR FURTHER INFORMATION CONTACT:** Micah Caldwell, Consumer and Governmental Affairs Bureau at (202) 418-1316 or by email at [Micah.Caldwell@fcc.gov](mailto:Micah.Caldwell@fcc.gov).

**SUPPLEMENTARY INFORMATION:** The Commission's Order, *Termination of*

*Certain Proceedings as Dormant*, document DA 18–13, adopted on January 5, 2018, and released on January 5, 2018, is available in CG Docket No. 17–22. The full text of document DA 18–13, the spreadsheet associated with document DA 18–13 listing the proceedings terminated as dormant, and copies of any subsequently filed documents in this matter will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. The full text of these documents and any subsequently filed documents in this matter may also be found by searching ECFS at: <https://www.fcc.gov/ecfs/>. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

**Gregory V. Haledjian,**

*Legal Advisor, Consumer and Governmental Affairs Bureau.*

[FR Doc. 2018–01409 Filed 2–2–18; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### Federal Advisory Committee Act; Technological Advisory Council

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting.

**DATES:** Wednesday, March 7th, 2018 in the Commission Meeting Room, from 10:00 a.m. to 3:00 p.m.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Walter Johnston, Chief, Electromagnetic Compatibility Division, 202–418–0807; [Walter.Johnston@FCC.gov](mailto:Walter.Johnston@FCC.gov).

**SUPPLEMENTARY INFORMATION:** This is the first meeting of the Technological Advisory Council for 2018. At its prior meeting on December 6th, 2017, the Council had discussed possible work initiatives for 2018. These initiatives have been discussed in the interim within the FCC, with the TAC chairman,

as well as with individual TAC members. At the June meeting, the FCC Technological Advisory Council will discuss its proposed work program for 2018. The FCC will attempt to accommodate as many people as possible. However, admittance will be limited to seating availability. Meetings are also broadcast live with open captioning over the internet from the FCC Live web page at <http://www.fcc.gov/live/>. The public may submit written comments before the meeting to: Walter Johnston, the FCC's Designated Federal Officer for Technological Advisory Council by email: [Walter.Johnston@fcc.gov](mailto:Walter.Johnston@fcc.gov) or U.S. Postal Service Mail (Walter Johnston, Federal Communications Commission, Room 2–A665, 445 12th Street SW, Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or by calling the Office of Engineering and Technology at (202) 418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

**Julius P. Knapp,**

*Chief, Office of Engineering and Technology.*

[FR Doc. 2018–02196 Filed 2–2–18; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1189]

### Information Collection Being Reviewed by the Federal Communications Commission

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of

information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written PRA comments should be submitted on or before April 6, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email to [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060–1189.

*Title:* Signal Boosters, Sections 1.1307(b)(1), 20.3, 20.21(a)(2), \* 5749 20.21(a)(5), 20.21(e)(2), 20.21(e)(8)(I)(G), 20.21(e)(9)(I)(H), 20.21(f), 20.21(h), 22.9, 24.9, 27.9, 90.203, 90.219(b)(1)(I), 90.219(d)(5), and 90.219(e)(5).

*Form Number:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit entities, Not for profit institutions and Individuals or household.

*Number of Respondents and Responses:* 632,595 respondents and 635,215 responses.

*Estimated Time per Response:* .5 hours–40 hours.

*Frequency of Response:*

Recordkeeping requirement, On occasion reporting requirement and Third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for this information collection is contained in 47 U.S.C. 154(l), 303(g), 303(r) and 332.

*Total Annual Burden:* 324,470 hours.

*Total Annual Cost:* No cost.

*Privacy Impact Assessment:* This information collection affects individuals or households; thus, there are impacts under the Privacy Act. However, the government is not directly collecting this information and the R&O directs carriers to protect the information to the extent it is considered Customer Proprietary Network Information (CPNI).

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Needs and Uses:* The Commission is seeking approval from the Office of Management and Budget (OMB) approval for a three year time period for this information collection requirements approved under this collection. The following information collection requirements are approved under this collection:

*Labeling Requirements. Sections 20.21(a)(5), 20.21(f), 90.219(e)(5)*—In order to avoid consumer confusion and provide consumers with needed information, the Commission adopted labeling requirements for Consumer and Industrial Signal Boosters. Consumer Signal Boosters must be labeled to identify the device as a “consumer” device and make the consumer aware that the device must be registered; may only be operated with the consent of the consumer’s wireless provider; may only be operated with approved antennas and cables; and that E911 communications may be affected for calls served by using the device. Industrial Signal Boosters must include a label stating that the device is not a consumer device, is designed for installation by FCC licensees or a qualified installer, and the operator must have a FCC license or consent of a FCC licensee to operate the device. Accordingly, all signal boosters marketed on or after March 1, 2014, must include the advisories (1) in on-line point-of-sale marketing materials; (2) in any print or on-line owner’s manual and installation instructions; (3) on the outside packaging of the device; and (4) on a label affixed to the device. Part 90 signal boosters marketed or sold on or after March 1, 2014, must include a label stating that the device is not a consumer device; the operator must have a FCC license or consent of a FCC licensee to operate the device; the operator must register Class B signal boosters; and unauthorized use may result in significant forfeitures.

*Section 20.21(f)(1)(iv)(A)(2)*—In order to ensure that consumers are properly informed about which devices are suitable for their use and how to comply with our rules, the Commission required

that all Consumer Signal Boosters certified for fixed, in-building operation include a label directing consumers that the device may only be operated in a fixed, in-building location. The Verizon Petitioners state that this additional labeling requirement is necessary to inform purchasers of fixed Consumer Signal Boosters that they may not lawfully be installed and operated in a moving vehicle or outdoor location. We recognize that our labeling requirement imposes additional costs on entities that manufacture Consumer Signal Boosters; however, on balance, we find that such costs are outweighed by the benefits of ensuring that consumers purchase appropriate devices. Accordingly, all fixed Consumer Signal Boosters, both Provider-Specific and Wideband, manufactured or imported on or after one year from the effective date of the rule change must include the following advisory (1) in on-line point-of-sale marketing materials, (2) in any print or on-line owner’s manual and installation instructions, (3) on the outside packaging of the device, and (4) on a label affixed to the device: “This device may be operated ONLY in a fixed location for in-building use.”

*Section 1.1307(b)(1)—Radiofrequency (RF).* This rule requires that a label is affixed to the transmitting antenna that provides adequate notice regarding potential RF safety hazards and references the applicable FCC-adopted limits for RF exposure.

*Provider Reporting Requirement:* In order to facilitate review of wireless providers’ behavior regarding Consumer Signal Boosters, the R&O requires that on March 1, 2015, and March 1, 2016, all nationwide wireless providers publicly indicate their status regarding consent for each Consumer Signal Booster that has received FCC certification as listed in a Public Notice to be released by the Wireless Telecommunications Bureau 30 days prior to each reporting date. For each listed Consumer Signal Booster, wireless providers should publicly indicate whether they (1) consent to use of the device; (2) do not consent to use of the device; or (3) are still considering whether or not they will consent to the use of the device.

*Registration Requirements: Section 20.21(a)(2)*—The rules require signal booster operators to register Consumer Signal Boosters, existing and new, with their serving wireless providers prior to operation. This is a mandatory requirement to continue or begin operation of a Consumer Signal Booster. The registration requirement will aid in interference resolution and facilitate

provider control over Consumer Signal Boosters.

The information collection contained in Section 20.21(a)(2) affects individuals or households; thus, there are impacts under the Privacy Act. However, the government is not directly collecting this information and the R&O directs carriers to protect the information to the extent it is considered Customer Proprietary Network Information (CPNI).

*Section 20.21(h)*—By March 1, 2014, all providers who voluntarily consent to the use of Consumer Signal Boosters on their networks must establish a free registration system for their subscribers. At a minimum, providers must collect (1) the name of the Consumer Signal Booster owner and/or operator, if different individuals; (2) the make, model, and serial number of the device; (3) the location of the device; and (4) the date of initial operation. Otherwise, the Commission permits providers to develop their own registration systems to facilitate provider control and interference resolution, providers should collect only such information that is reasonably related to achieving these dual goals. Wireless providers may determine how to collect such information and how to keep it up-to-date.

*Section 90.219(d)(5)*—This rule requires operators of Part 90 Class B signal boosters to register these devices in a searchable on-line database that will be maintained and operated by the Wireless Telecommunications Bureau via delegated authority from the Commission. The Commission believes this will be a valuable tool to resolve interference should it occur.

*Certification Requirements: Sections 20.3, 20.21(e)(2), 20.21(e)(8)(i)(G), 20.21(e)(9)(i)(H), 90.203*—These rules, in conjunction with the R&O, require that signal booster manufacturers demonstrate that they meet the new technical specifications using the existing and unchanged equipment authorization application, including submitting a technical document with the application for FCC equipment authorization that shows compliance of all antennas, cables and/or coupling devices with the requirements of § 20.21(e). The R&O further provides that manufacturers must make certain certifications when applying for device certification. Manufacturers must provide an explanation of all measures taken to ensure that the technical safeguards designed to inhibit harmful interference and protect wireless networks cannot be deactivated by the user. The R&O requires that manufacturers of Provider-Specific

Consumer Signal Boosters may only be certificated with the consent of the licensee so the manufacturer must certify that it has obtained such consent as part of the equipment certification process. The R&O also requires that if a manufacturer claims that a device will not affect E911 communications, the manufacturer must certify this claim during the equipment certification process. **Note:** The “application for equipment” certification requirements are met under OMB Control Number 3060–0057, FCC Form 731.

*Antenna Kitting Documentation Requirement: Sections 20.21(e)(8)(i)(G), 20.21(e)(9)(i)(H)*—The rules require that all consumer boosters must be sold with user manuals specifying all antennas and cables that meet the requirements of this section.

*Part 90 Licensee Consent Documentation Requirement: Section 90.219(b)(1)(i)*—This rule requires that non-licensees seeking to operate part 90 signal boosters must obtain the express consent of the licensee(s) of the frequencies for which the device or system is intended to amplify. The rules further require that such consent must be maintained in a recordable format that can be presented to a FCC representative or other relevant licensee investigating interference.

*Cross-reference to Other Rule Parts: Sections 22.9, 24.9, and 27.9*—Operation of a consumer signal booster under Parts 22, 24, and 27 of the Commission’s rules must also comply with section 20.21 of the Commission’s rules, including all relevant information collections.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2018–02194 Filed 2–2–18; 8:45 am]

**BILLING CODE 6712–01–P**

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## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice to All Interested Parties of Intent To Terminate the Receivership of 10424, Charter National Bank and Trust, Hoffman Estates, Illinois

*Notice is hereby given* that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for Charter National Bank and Trust, Hoffman Estates, Illinois, intends to terminate its receivership for said institution. The FDIC was appointed Receiver of Charter National Bank and Trust on February 10, 2012. The liquidation of the receivership assets has been completed. To the extent permitted by available

funds and in accordance with law, the receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201. No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: January 30, 2018.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2018–02165 Filed 2–2–18; 8:45 am]

**BILLING CODE 6714–01–P**

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## FEDERAL ELECTION COMMISSION

### Sunshine Act Meeting

**TIME AND DATE:** Thursday, February 8, 2018 at 11:00 a.m.

**PLACE:** 999 E Street NW, Washington, DC (Ninth Floor).

**STATUS:** This meeting will be open to the public.

**MATTERS TO BE CONSIDERED:**

Draft Advisory Opinion 2017–13:  
National Sorghum Producers and Sorghum PAC

Proposed Final Audit Report on the Hawaii Democratic Party (A13–07)  
Management and Administrative Matters

**CONTACT PERSON FOR MORE INFORMATION:**  
Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

**Dayna C. Brown,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2018–02360 Filed 2–1–18; 4:15 pm]

**BILLING CODE 6715–01–P**

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## FEDERAL ELECTION COMMISSION

### Sunshine Act Notice

**TIME AND DATE:** Thursday, February 8, 2018 at 10:00 a.m.

**PLACE:** 999 E Street NW, Washington, DC (Ninth Floor).

**STATUS:** This hearing will be open to the public.

**MATTER TO BE CONSIDERED:**

Audit Hearing: McSally for Congress

**CONTACT PERSON FOR MORE INFORMATION:**  
Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

**Dayna C. Brown,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2018–02355 Filed 2–1–18; 4:15 pm]

**BILLING CODE 6715–01–P**

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## FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS18–01]

### Appraisal Subcommittee; Notice of Meeting

**AGENCY:** Appraisal Subcommittee of the Federal Financial Institutions Examination Council

**ACTION:** Notice of meeting.

*Description:* In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

*Location:* Federal Reserve Board—International Square location, 1850 K Street NW, Washington, DC 20006.

*Date:* February 14, 2018.

*Time:* 10:00 a.m.

*Status:* Open.

*Reports:*

Chairman

Executive Director

Delegated State Compliance Reviews  
Financial Report

*Action and Discussion Items:*

November 8, 2017 Open Session  
Minutes

Revised ASC Policy Statements  
Appraisal Foundation FY17 Grant  
Reprogramming Request

*How to Attend and Observe an ASC meeting:*

If you plan to attend the ASC Meeting in person, we ask that you send an email to [meetings@asc.gov](mailto:meetings@asc.gov). You may register until close of business four business days before the meeting date. You will be contacted by the Federal Reserve Law Enforcement Unit on security requirements. You will also be asked to provide a valid government-issued ID before being admitted to the Meeting. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: January 31, 2018.

**James R. Park,**

*Executive Director.*

[FR Doc. 2018-02247 Filed 2-2-18; 8:45 am]

BILLING CODE 6700-01-P

## GENERAL SERVICES ADMINISTRATION

[Notice-PBS-2018-02; Docket No. 2018-0002; Sequence No. 2]

### Notice of Scoping Meeting and Intent to Prepare a Supplemental Environmental Impact Statement (SEIS) for the Madawaska-Edmundston International Bridge and New Land Port of Entry (LPOE) Project

**AGENCY:** Public Building Service (PBS), General Services Administration (GSA).

**ACTION:** Notice of intent; announcement of meeting.

**SUMMARY:** Pursuant to the requirements of the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality Regulations, and the GSA Public Buildings Service NEPA Desk Guide, GSA is issuing this notice to advise the public that a Supplemental Environmental Impact Statement (SEIS) will be prepared for the proposed construction of the Madawaska-Edmundston International Bridge and New Land Port of Entry (the Project).

**DATES:** *Meeting Date:* The Public Information and Scoping Session will be held on Wednesday, January 31, 2018, at 7:00 p.m., EST (Eastern Standard Time). Interested parties are encouraged to provide written comments on or before Monday, February 28, 2018.

**ADDRESSES:** Madawaska High School Cafeteria, 135 7th Avenue, Madawaska, Maine 04756. The session format includes a 30-minute Open House,

followed by formal presentation and Question & Answer session.

Written comments can be submitted by either of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the Notice number. Select the link "Comment Now" that corresponds with "PBS-2018-02, Notice of Scoping Meeting and Intent to Prepare a Supplemental Environmental Impact Statement (SEIS) for the Madawaska-Edmundston International Bridge and New Land Port of Entry (LPOE) Project." Follow the instructions provided on the screen. Please include your name, company name (if any), and "PBS-2018-02, Notice of Scoping Meeting and Intent to Prepare a Supplemental Environmental Impact Statement (SEIS) for the Madawaska-Edmundston International Bridge and New Land Port of Entry (LPOE) Project" on your attached document.

- *Postal Mail:* Ms. Alexas Kelly, Project Manager, GSA, 10 Causeway Street, 11th Floor, Boston, MA 02222.

#### FOR FURTHER INFORMATION CONTACT:

Alexas Kelly, Project Manager, GSA, New England Region, at email [alexandria.kelly@gsa.gov](mailto:alexandria.kelly@gsa.gov), or call 617-549-8190. Please also call this number if special assistance is needed to attend and participate in the public scoping meeting.

#### SUPPLEMENTARY INFORMATION:

##### Background

The purpose of the Project is to provide for the long-term safe and efficient flow of current and projected traffic volumes, including the movement of goods and people between Edmundston, New Brunswick and Madawaska, Maine. The Project is needed because (1) the existing International Bridge is nearing the end of its useful life, and (2) the existing Madawaska Land Port of Entry is substandard, inhibiting the agencies assigned to the Port from adequately fulfilling their respective missions.

The existing Madawaska-Edmundston International Bridge, opened in 1921, and its design life has exceeded. Notable bridge deficiencies are (1) substandard geometry—roadway width & clearance, (2) foundation susceptible to undermining, (3) piers cracked and deteriorated, (4) significant steel corrosion, (5) bridge capacity is insufficient, and (6) deficiencies prompting the bridge posting on October 27, 2017, from 50 tons to 5 tons.

A Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) were published in January 2007,

which addressed the construction of a new Madawaska LPOE.

Built in 1959, the current LPOE suffers from facility, operational and site deficiencies, and does not meet current Customs and Border Protection (CBP) mission & operational requirements for an LPOE. A few noted deficiencies: (1) Lack of office and inspection areas, (2) deficient inbound and outbound passenger and commercial processing areas, (3) inadequate queuing space for vehicles, and (4) inability to meet the Architectural Barriers Act. In furtherance of the LPOE Project, GSA previously acquired approximately nine acres of land, but did not commence construction.

An SEIS is needed due to a change in circumstance, specifically the decision by MaineDOT and New Brunswick Department of Transportation and Infrastructure (NBTI), which requires the existing Edmundston/Madawaska International Bridge be replaced and removed. The SEIS will address changes to the Project, including an updated design in accordance with current GSA and CBP requirements, and a reconfigured International Bridge approach (the totality of which may require additional land acquisition).

#### Scoping Process and Next Steps

Scoping will be accomplished through this public meeting, and direct mail correspondence, to appropriate Federal, state, and local agencies, and to private organizations and citizens who have previously expressed, or are known to have, an interest in the Project.

The primary purpose of the scoping process is for the public to assist GSA in developing the SEIS by identifying and determining the range and extent of relevant issues related to the Project. Alternatives will be developed with input from the local community through the scoping process. GSA will provide public notice of this and any subsequent public meetings in local newspapers, radio announcements, postings in prominent town locations, and other outreach actions.

Dated: January 29, 2018.

**Drew Dilks,**

*Project Management Branch Chief, Design and Construction, Public Buildings Service.*

[FR Doc. 2018-02164 Filed 2-2-18; 8:45 am]

BILLING CODE 6820-23-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day–18–17BAM]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Implementing the 6/18 Initiative: Case Studies* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on October 13, 2017 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202)

395–5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

Implementing the 6|18 Initiative: Case Studies—New—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Major trends in health care, such as alternative payment and delivery models, facilitate the delivery of greater comprehensive care and prevention. Public health departments have leveraged their resources to complement those of the health care sector, to impact population health.

In this context, CDC developed the CDC’s 6|18 Initiative to provide health care purchasers, payers, and providers with rigorous evidence about high-burden health conditions and associated evidence-based interventions. With a focus on the greatest short-term health and potential cost impact (generally in less than five years), the evidence informs their coverage decisions.

The name “6|18” comes from the initial focus on six common, costly and preventable health conditions (tobacco use, high blood pressure, diabetes, asthma, healthcare-associated infections and unintended pregnancies) and 18 evidence-based interventions. For more information, please see <http://www.cdc.gov/sixeighteen>.

The 6|18 initiative links health care and public health by providing a shared focus across prevention interventions ranging from traditional clinical settings to care outside the clinical setting. Public health’s strength in analyzing scientific evidence complements the purchaser, payer, and provider role of financing and delivering care.

Since public health-health care collaboration to improve population health is still not a standard practice, there are few or no case studies on public health-health care collaboration around increasing preventive service utilization. CDC intends to fill this gap through this data collection.

CDC and its partners provided technical assistance to 17 teams (i.e., from Medicaid and Public Health Agencies) from states, the District of Columbia, and a large city (hereafter, “states”), to support their implementation of the 6|18 Initiative’s interventions. No data has been collected to date.

To document qualitative lessons learned related to the collaboration, CDC and its cooperative agreement sub-contractor, George Washington University, plan to conduct in-person and telephone semi-structured

individual interviews with state Public Health Department and State Medicaid Agency officials.

Interview participants will have been directly involved in conceptualizing, planning, and/or implementing 6|18 Initiative-related activities, and will have participated in the cross-sector collaboration. CDC plans to engage up to 82 respondents (four to seven officials from each of the 17 state teams who participated in the 6|18 Initiative). The officials from each state team will be leadership and staff from public health agencies at the state, city, and tribal level. For each state, we will request interviews with: One Public Health Division Director, one to four Public Health Services Managers (one per health condition), one Medicaid Director, and one Medicaid Services Manager. When joining the 6|18 Initiative, each state selected one to four conditions from the list of 6|18 conditions, and assigned one public health manager to each condition.

CDC plans to administer the interviews from 2018 to 2021, to allow time for unanticipated delays; and to accommodate state team schedules, busy seasons, and holidays. All participants will speak in their official capacity as state public health department or Medicaid agency officials. Prior to granting public access to written products, CDC will provide participants the opportunity to review written products.

CDC anticipates using the interview findings: (1) To describe, disseminate, and scale best practices to participating and non-participating states, and (2) for program improvement of the CDC’s 6|18 Initiative. CDC will disseminate findings via written products such as peer-reviewed manuscripts and in-depth written case studies. The written products, which will share lessons learned and effective approaches to collaboration, can inform and potentially accelerate related efforts by other state teams. In addition, 6|18 participants can use findings and written products to highlight their accomplishments to their stakeholders, such as their Medicaid leadership, and/or governors.

Participants will have a maximum estimated burden of one hour and 15 minutes: One hour for the interview, and fifteen minutes for any needed preparation. All interviews will be based on the same interview guide.

OMB approval is requested for three years. An annualized average of 29 interviews will be conducted per year. Participation is voluntary and respondents will not receive incentives for participation. There are no costs to

respondents other than their time. The total estimated annualized burden hours are 38.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents                | Form name             | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|------------------------------------|-----------------------|-----------------------|------------------------------------|--|
| State Public Health Director ..... | Interview Guide ..... | 6                     | 1                                  | 75/60                                  |
| State Public Health Manager .....  | Interview Guide ..... | 11                    | 1                                  | 75/60                                  |
| State Medicaid Director .....      | Interview Guide ..... | 6                     | 1                                  | 75/60                                  |
| State Medicaid Manager .....       | Interview Guide ..... | 6                     | 1                                  | 75/60                                  |

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.

[FR Doc. 2018-02205 Filed 2-2-18; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Centers for Disease Control and  
 Prevention**

[60Day-18-0307; Docket No. CDC-2018-0019]

**Proposed Data Collection Submitted  
 for Public Comment and  
 Recommendations**

**AGENCY:** Centers for Disease Control and  
 Prevention (CDC), Department of Health  
 and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease  
 Control and Prevention (CDC), as part of  
 its continuing effort to reduce public  
 burden and maximize the utility of  
 government information, invites the  
 general public and other Federal  
 agencies the opportunity to comment on  
 a proposed and/or continuing  
 information collection, as required by  
 the Paperwork Reduction Act of 1995.  
 This notice invites comment on a  
 proposed information collection project  
 titled “Gonococcal Isolate Surveillance  
 Project (GISP)”. The purpose of GISP is  
 to monitor trends in antimicrobial  
 resistance in *N. gonorrhoeae* strains in  
 the United States in order to establish a  
 scientific basis for the selection of  
 gonococcal therapies and to allow  
 proactive changes to treatment  
 guidelines before widespread resistance  
 and failures of treatment occur.

**DATES:** CDC must receive written  
 comments on or before April 6, 2018.

**ADDRESSES:** You may submit comments,  
 identified by Docket No. CDC-2018-  
 0019 by any of the following methods:

- *Federal eRulemaking Portal:*  
*Regulations.gov.* Follow the instructions for  
 submitting comments.

- *Mail:* Leroy A. Richardson, Information  
 Collection Review Office, Centers for Disease  
 Control and Prevention, 1600 Clifton Road  
 NE, MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received  
 must include the agency name and  
 Docket Number. CDC will post, without  
 change, all relevant comments to  
*Regulations.gov.*

**Please note:** Submit all comments through  
 the Federal eRulemaking portal  
 (*regulations.gov*) or by U.S. mail to the  
 address listed above.

**FOR FURTHER INFORMATION CONTACT:** To  
 request more information on the  
 proposed project or to obtain a copy of  
 the information collection plan and  
 instruments, contact Leroy A.  
 Richardson, Information Collection  
 Review Office, Centers for Disease  
 Control and Prevention, 1600 Clifton  
 Road NE, MS-D74, Atlanta, Georgia  
 30329; phone: 404-639-7570; Email:  
*omb@cdc.gov.*

**SUPPLEMENTARY INFORMATION:** Under the  
 Paperwork Reduction Act of 1995 (PRA)  
 (44 U.S.C. 3501-3520), Federal agencies  
 must obtain approval from the Office of  
 Management and Budget (OMB) for each  
 collection of information they conduct  
 or sponsor. In addition, the PRA also  
 requires Federal agencies to provide a  
 60-day notice in the **Federal Register**  
 concerning each proposed collection of  
 information, including each new  
 proposed collection, each proposed  
 extension of existing collection of  
 information, and each reinstatement of  
 previously approved information  
 collection before submitting the  
 collection to the OMB for approval. To  
 comply with this requirement, we are  
 publishing this notice of a proposed  
 data collection as described below.

The OMB is particularly interested in  
 comments that will help:

1. Evaluate whether the proposed  
 collection of information is necessary  
 for the proper performance of the  
 functions of the agency, including

whether the information will have  
 practical utility;

2. Evaluate the accuracy of the  
 agency’s estimate of the burden of the  
 proposed collection of information,  
 including the validity of the  
 methodology and assumptions used;

3. Enhance the quality, utility, and  
 clarity of the information to be  
 collected; and

4. Minimize the burden of the  
 collection of information on those who  
 are to respond, including through the  
 use of appropriate automated,  
 electronic, mechanical, or other  
 technological collection techniques or  
 other forms of information technology,  
*e.g.*, permitting electronic submissions  
 of responses.

5. Assess information collection costs.

**Proposed Project**

Gonococcal Isolate Surveillance  
 Project (OMB Control Number 0920-  
 0307, Expiration 2/28/2019)—  
 Revision—National Center for HIV/  
 AIDS, Viral Hepatitis, STD, and TB  
 Prevention (NCHHSTP), Centers for  
 Disease Control and Prevention (CDC).

**Background and Brief Description**

The Gonococcal Isolate Surveillance  
 Project (GISP) was created in 1986 to  
 monitor trends in antimicrobial  
 susceptibilities of *N. gonorrhoeae*  
 strains in the United States. Data from  
 GISP are used to establish a scientific  
 basis for the selection of gonococcal  
 therapies and to allow pro-active  
 changes to treatment guidelines before  
 widespread resistance and failures of  
 treatment occur. To increase capacity to  
 detect and monitor resistant gonorrhea  
 and improve the specificity of GISP, this  
 submission is a revision to include  
 collection of additional isolates and data  
 elements.

The Centers for Disease Control and  
 Prevention has designated *N.*  
*gonorrhoeae* as one of three “urgent”  
 antibiotic resistance threats in the  
 United States. The CDC is requesting a  
 three-year OMB approval for this  
 revision, which directly responds to the

National Strategy for Combating Antibiotic Resistant Bacteria by improving and strengthening surveillance of antimicrobial resistance

through GISP. Additionally, data from GISP will also allow CDC to monitor and evaluate the effectiveness of public health interventions conducted to

support the National Strategy for Combating Antibiotic Resistant Bacteria. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents                             | Form name                                     | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|-----------------------|------------------------------------|--|-------------------------|
| Sentinel site conducting core surveillance.     | Demographic/Clinical Data .....               | 20                    | 240                                | 11/60                                  | 880                     |
| Sentinel site conducting enhanced surveillance. | Demographic/Clinical Data .....               | 10                    | 840                                | 12/60                                  | 1,680                   |
| Regional laboratory .....                       | Antimicrobial Susceptibility Testing Results. | 4                     | 3,300                              | 40/60                                  | 8,800                   |
| Regional laboratory .....                       | Control Strain Susceptibility Testing         | 4                     | 48                                 | 5/60                                   | 16                      |
| Total .....                                     | .....   | .....                 | .....                              | .....                                  | 11,376                  |

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018-02222 Filed 2-2-18; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-18-0773]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Surveillance for Severe Adverse Events Among Persons on Treatment of Latent Tuberculosis Infection to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on August 22, 2017 to obtain comments from the public and affected agencies. CDC received one substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection—(0920-0773, expiration 01/31/2018)—Extension—Division of Tuberculosis Elimination (DTBE), National Center for HIV, Viral Hepatitis, STD, and TB Prevention NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

This project seeks a three-year extension to continue the passive reporting system for severe adverse events (SAEs) associated with therapy for Latent Tuberculosis Infection (LTBI). The system will rely on medical chart review and/or onsite investigations by TB control staff. In 2004, CDC began collecting reports of SAEs associated with any treatment regimen for LTBI. For surveillance purposes, an SAE was defined as any drug-associated reaction resulting in a patient’s hospitalization or death after at least one treatment dose for LTBI. Reports of SAEs related to rifampicin plus pyrazinamide (RZ) and isoniazid (INH) INH have prompted a need for this project a national surveillance system of such events.

The objective of the project is to determine the annual number and temporal trends of SAEs associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation or potential revision of guidelines for treatment of persons with LTBI.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for SAEs associated with LTBI treatment. The data collection form is completed by healthcare providers and health departments for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. Reporting of SAEs will be conducted through telephone, email, or during CDC site visits.

CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and will conduct special analyses for

publication in peer-reviewed scientific journals to further describe and interpret these data.

In this extension request, CDC is requesting approval for approximately

60 burden hours annually. There is no cost to respondents.

**Estimated Annualized Burden Hours**

| Type of respondent  | Form name   | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---------------------|-------------|-----------------------|------------------------------------|--|
| Physician .....     | NSSAE ..... | 10                    | 1                                  | 1                                      |
| Nurse .....         | NSSAE ..... | 10                    | 1                                  | 4                                      |
| Medical Clerk ..... | NSSAE ..... | 10                    | 1                                  | 1                                      |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018-02206 Filed 2-2-18; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* National and Tribal Evaluation of the 2nd Generation of the Health Profession Opportunity Grants.

*OMB NO.:* 0970-0462.

*Description:* The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of the Health Profession Opportunity Grants (HPOG) to serve TANF and Other Low Income Individuals. ACF has developed a multi-pronged research and evaluation approach for the HPOG Program to better understand and assess the activities conducted and their results. Two rounds of HPOG grants have been awarded—the first in 2010 (HPOG 1.0) and the second in 2015 (HPOG 2.0). There are federal evaluations associated with each round of grants. HPOG grants provide funding to government agencies, community-based organizations, post-secondary educational institutions, and tribal-affiliated organizations to provide education and training services to

Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals, including tribal members. Under HPOG 2.0, ACF provided grants to five tribal-affiliated organizations and 27 non-tribal entities.

OMB previously approved data collection under OMB Control Number 0970-0462 for: the HPOG 2.0 National and Tribal Evaluation (Approved August 2015); and the National Evaluation impact study; the National Evaluation descriptive study; and the Tribal Evaluation (All approved June 2017). The proposed data collection activities described in this **Federal Register** Notice will provide data for the impact and cost benefit studies of the 27 non-tribal grantees participating in the National Evaluation of HPOG 2.0.

*National Evaluation:* The National Evaluation pertains only to the 27 non-tribal grantees that received HPOG 2.0 funding. The design for the National Evaluation features an implementation study, a systems change analysis, and cost benefit analysis. In addition, the National Evaluation is using an experimental design to measure and analyze key participant outcomes including completion of education and training, receipt of certificates and/or degrees, earnings, and employment in a healthcare career. The impact evaluation will assess the outcomes for study participants that were offered HPOG 2.0 training, financial assistance, and support services, compared to what their outcomes would have been if they had not been offered HPOG 2.0 services. This Notice provides the opportunity to comment on a proposed new information collection activity for the HPOG 2.0 National Evaluation’s impact study—the HPOG 2.0 Impact Evaluation

first follow-up survey, referred to as the Short-Term Follow-up Survey. The first follow-up survey of both treatment and control group members will be administered approximately 15 months after baseline data collection and random assignment. The survey will collect data about key outcomes of interest, including participants’ tenure and experience in HPOG programming; certifications and educational achievements; job placement; and receipt of benefits. These are the key outcomes of interest for which data are not otherwise available through existing data sources. Previously approved collection activities under 0970-0462 will continue under this new request for the National Evaluation of the non-tribal grantees.

In subsequent requests for clearance, we will submit (1) additional data collection instruments to support the descriptive study of the 27 non-tribal grantees participating in the HPOG 2.0 National Evaluation, including grantee interview guides and participant interview guides; and (2) the second follow-up survey—the Intermediate Follow-up Survey—for the HPOG 2.0 National Evaluation impact study. The second follow-up survey is for collecting data from both treatment and control group members at the 27 non-tribal grantees, approximately 36 months after baseline data collection and random assignment. This submission will also include data collection necessary for the National Evaluation’s cost benefit analysis.

*Respondents:* For the National Evaluation impact study: HPOG 2.0 study participants at the 27 non-tribal grantees.

## ANNUAL BURDEN ESTIMATES

[This information collection request is for 3 years]

| Instrument   | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| 1. National Evaluation 15-Month Follow-up Survey ..... | 10,400                      | 3,467                        | 1                                  | 1                                 | 3,467               |

*Estimated Total Annual Burden Hours: 3,467.*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Mary Jones,**  
*ACF/OPRE Certifying Officer.*

[FR Doc. 2018-02238 Filed 2-2-18; 8:45 am]

BILLING CODE 4184-72-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2016-E-1276; FDA-2016-E-1277; and FDA-2016-E-1278]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VIBERZI

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VIBERZI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the

Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 6, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 6, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 6, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket Nos. FDA-2016-E-1276; FDA-2016-E-1277 and FDA-2016-E-1278 for "Determination of Regulatory Review Period for Purposes of Patent Extension; VIBERZI." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on

<https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory

review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product VIBERZI (eluxadoline). VIBERZI is indicated in adults for the treatment of irritable bowel syndrome with diarrhea. Subsequent to this approval, the USPTO received patent term restoration applications for VIBERZI (U.S. Patent Nos. 7,741,356; 8,344,011; and 8,609,709) from Janssen Pharmaceutica, N.V., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated August 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VIBERZI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

**II. Determination of Regulatory Review Period**

FDA has determined that the applicable regulatory review period for VIBERZI is 2,716 days. Of this time, 2,381 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:*

December 21, 2007. FDA has verified the applicant’s claim that December 21, 2007, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 27, 2014.

The applicant claims June 26, 2014, as the date the new drug application (NDA) for VIBERZI was initially submitted. However, FDA records indicate that NDA 206940 was submitted on July 27, 2014, which is considered to be the NDA initially submitted date.

3. *The date the application was approved:* May 27, 2015. FDA has verified the applicant’s claims that NDA 206940 was approved on May 27, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 428 days, 606 days, or 431 days of patent term extension.

**III. Petitions**

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket Nos. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-02187 Filed 2-2-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-0388]

**Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled “Hazard Analysis and Risk-

Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability” that appeared in the **Federal Register** of January 23, 2018. The document announced the availability of a draft guidance for industry #245 entitled “Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.” The document was published with the incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Tuesday, January 23, 2018 (83 FR 3163), in FR Doc. 2018-01126, on page 3163, the following correction is made:

1. On page 3163, in the first column, in the header of the document, the docket number is corrected to read “FDA-2018-D-0388”.

Dated: January 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-02181 Filed 2-2-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-2428]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug Adverse Event Reporting and Recordkeeping

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 7, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-

395-7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0284. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Animal Drug Adverse Event Reporting and Recordkeeping—21 U.S.C. 360b(l), 21 CFR 510.301, and 514.80

*OMB Control Number 0910-0284—Extension*

With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4). Sections 571(e)(3) and 512(e)(2) of the FD&C Act (21 U.S.C. 360ccc(e)(3) and 360b(e)(2)) require that applicants with conditionally approved new animal drug applications (CNADAs) maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l). Finally, section 512(m)(5) of the FD&C Act requires an applicant for a license to manufacture animal feeds bearing or containing new animal drugs to maintain adequate records and make reports “as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine” whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) or a license to manufacture animal feeds

bearing or containing new animal drugs under section 512(m)(4).

Section 514.80 of our regulations (21 CFR 514.80) sets forth the recordkeeping and reporting requirements for applicants and nonapplicants of approved NADAs and ANADAs. Section 510.301 of our regulations (21 CFR 510.301) sets forth the recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities.

*Recordkeeping and reporting requirements for applicants of approved NADAs and ANADAs.* Section 514.80 requires applicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians or following their own detection of a problem, applicants are required to submit adverse event reports and product defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) on Form FDA 1932. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the general public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 2301 is used by applicants to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug. We have made minor editorial revisions to Form FDA 1932a to clarify how to report adverse drug events associated with compounded products using that form. Submitters are already reporting adverse drug events associated with compounded products on Form FDA 1932a. The clarifications include: the addition of a new question, “Is this a compounded product?”; the addition of a new field to allow the submitter to provide product strength, “Strength of Active Ingredient(s)”; modifying the title of the existing field requesting the name of manufacturer, so that it reads, “Name of Manufacturer or Compounding Pharmacy/Compounder of Suspected Product”; and a request for contact information for the manufacturer or compounder. We estimate that the revisions will not change the average amount of time necessary to complete the form.

*Recordkeeping and reporting requirements for applicants of CNADAs.* As noted, sections 571(e)(3) and 512(e)(2) of the FD&C Act require that applicants for CNADAs maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l) of the FD&C Act. Moreover, section 512(l) requires submission of such information as required “by general regulation, or by order . . .” Conditional approval letters explicitly establish an order requiring the submission of postmarketing information in accordance with the requirements of § 514.80. Applicants submit adverse event reports and product defect reports on Form FDA 1932.

*Recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities.* Section 510.301 requires a licensed medicated feed manufacturer to keep records of and report to us information concerning experience with animal feeds bearing or containing approved new animal drugs. Under § 510.301(a), a licensed medicated feed manufacturer must immediately report to us information concerning any mixup in the new animal drug or its labeling; any bacterial or significant chemical, physical, or other change or deterioration in a drug; and any failure of one or more

distributed batches of a drug to meet the specifications established for it. Under § 510.301(b), a licensed medicated feed manufacturer must report to us within 15 working days of receipt of information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof, and any unusual failure of the new animal drug to exhibit its expected pharmacological activity. OMB initially approved the information collection provisions of § 510.301 under control number 0910–0012. That approval was subsequently consolidated into this collection in 2004. We reviewed the records and reports required by § 510.301 to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) of the FD&C Act, or grounds for revoking a license to manufacture medicated feed under section 512(m)(4).

Since the consolidation of the 0910–0012 collection into this collection in 2004, we have included the estimated number of medicated feed adverse event reports as part of our estimate of the number of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates, we have added a row to table 1, on which

we separately report our estimates of medicated feed reports.

The continuous monitoring of approved NADAs, ANADAs, CNADAs, and animal feeds bearing or containing new animal drugs affords the primary means by which we obtain information regarding potential problems with the safety and efficacy of marketed approved new animal drugs, as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to us may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

*Description of respondents:* Respondents to this collection of information are animal drug manufacturers with approved NADAs, ANADAs, or CNADAs, as well as licensed commercial feed mills and licensed mixer-feeders.

In the **Federal Register** of July 18, 2017 (82 FR 32829), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| Activity  | FDA Form | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours      |
|---|----------|-----------------------|------------------------------------|------------------------|-----------------------------|------------------|
| Medicated feed reports, § 510.301(a) and (b) .....  | N/A      | 5                     | 1                                  | 5                      | *0.25                       | 1.25             |
| Mandatory adverse event reporting, 21 U.S.C. 360b(l); § 514.80(b)(1); (b)(2)(i) and (ii); (b)(3); and (b)(4)(iv)(A) ..... | 1932     | 22                    | 81                                 | 1,782                  | 1                           | 1,782            |
| Voluntary adverse event reporting by veterinarians and the general public ....  | 1932a    | 197                   | 1                                  | 197                    | 1                           | 197              |
| Periodic drug experience reports, § 514.80(b)(4) .....  | 2301     | 200                   | 8.11                               | 1,622                  | 16                          | 25,952           |
| Special drug experience reports, § 514.80(b)(5)(i) .....  | 2301     | 200                   | 0.57                               | 114                    | 2                           | 228              |
| Submission of advertisements and promotional labeling, § 514.80(b)(5)(ii) .....   | 2301     | 200                   | 20.12                              | 4,024                  | 2                           | 8,048            |
| Submission of distributor statements, § 514.80(b)(5)(iii) .....   | 2301     | 190                   | 0.1                                | 19                     | 2                           | 38               |
| <b>Total</b> .....  |          |                       |                                    |                        |                             | <b>36,246.25</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

\* (15 minutes).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| Activity  | Number of record-keepers | Number of records per record-keeper | Total annual records | Average burden per record-keeping | Total hours   |
|---|--------------------------|-------------------------------------|----------------------|-----------------------------------|---------------|
| Recordkeeping, § 510.301 <sup>2</sup> .....                         | 5                        | 1                                   | 5                    | 4                                 | 20            |
| Recordkeeping, 21 U.S.C. 360b(l) and § 514.80(e) <sup>3</sup> ..... | 646.70                   | 7.19                                | 4,649.8              | 14                                | 65,097        |
| <b>Total</b> .....  |                          |                                     |                      |                                   | <b>65,117</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.

<sup>3</sup> This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and CNADAs under § 514.80(e).

We base our reporting and recordkeeping estimates on our

experience with adverse event reporting for approved new animal drugs and the

number of reports received in the previous 3 years. Since the

consolidation of the 0910–0012 collection into this collection in 2004, we have included the estimated recordkeeping burden for medicated feed adverse event reports as part of our estimate of the recordkeeping burden of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates we have added a row to table 2, on which we separately report our recordkeeping estimate for medicated feed adverse event reports (20 hours).

The burden of this collection has changed. There was a slight increase in the estimated number of reports submitted to FDA under total annual responses (by 7.8 responses) and there was a slight overall decrease in burden hours (by 1.75 hours). This minor fluctuation in responses and hours is due to the normal variation in the submission of reports to FDA, the correction of mathematical errors, and a change in reporting methodology (addition of a new row to table 1 and table 2).

We continually strive to improve our systems for collecting and analyzing drug experience reports and adverse event reports. To that end, we have developed an electronic submission system by which Form FDA 2301 may be submitted to the Agency. For Form FDA 1932a, we have a fillable electronic form available online, which can be submitted by email to FDA Center for Veterinary Medicine. We specifically invite comment from respondents on the utility of these reporting forms. Electronic adverse event reporting for approved new animal drugs (including mandatory reporting under § 514.80(b) and voluntary reporting) has been approved under OMB control number 0910–0645. Reporting and recordkeeping associated with the index of legally marketed unapproved new animal drugs for minor species (21 CFR part 516) is approved under OMB control number 0910–0620.

Dated: January 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–02234 Filed 2–2–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

**ACTION:** Notice of public meetings.

**SUMMARY:** This notice announces the 2018 meetings of the Physician-Focused Payment Model Technical Advisory Committee (hereafter referred to as “the Committee”) which will be held in Washington, DC. This meeting will include voting and deliberations on proposals for physician-focused payment models (PFPMs) submitted by members of the public. All meetings are open to the public.

**DATES:** The 2018 PTAC meetings will occur on the following dates:

- Monday–Tuesday, March 26–27, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, June 14–15, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, September 6–7, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, December 10–11, 2018, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

**ADDRESSES:** All PTAC meetings will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Ann Page, Designated Federal Official, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, 200 Independence Ave. SW, Washington, DC 20201, (202) 690–6870.

#### SUPPLEMENTARY INFORMATION:

I. *Purpose.* The Physician-Focused Payment Model Technical Advisory Committee (“the Committee”) is required by the Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. 1395ee. This Committee is also governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. In accordance with its statutory mandate, the Committee is to review physician-focused payment model proposals and prepare recommendations regarding whether such models meet criteria that were established through rulemaking by the Secretary of Health and Human Services (the Secretary). The Committee

is composed of 11 members appointed by the Comptroller General.

II. *Agenda.* At each scheduled meeting, the Committee will hear presentations on PFPMs that are ready for Committee deliberation. The presentations will be followed by public comment and Committee deliberation. If the Committee completes deliberations, voting will occur on recommendations to the Secretary of Health and Human Services. There will be time allocated for public comment on agenda items. Documents will be posted on the Committee website and distributed on the Committee listserv prior to the public meeting. The agenda is subject to change. If the agenda does change, we will inform registrants and update the website.

III. *Meeting Attendance.* These meetings are open to the public. The public may also attend via conference call or view the meeting via livestream at [www.hhs.gov/live](http://www.hhs.gov/live). The conference call dial-in information will be sent to registrants prior to the meeting.

*Meeting Registration:* The public may attend the meetings in-person, participate by phone via audio teleconference, or view the meeting via livestream. Space is limited and registration is preferred in order to attend in-person or by phone. Registration may be completed online at [www.regonline.com/PTACMeetings](http://www.regonline.com/PTACMeetings) Registration.

The following information is submitted when registering:

Name:  
Company/organization name:  
Postal address:  
Email address:

A confirmation email will be sent to registrants shortly after completing the registration process.

IV. *Special Accommodations.* If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Angela Tejada, no later than one week prior to the scheduled meeting. Please submit your requests by email to [Angela.Tejeda@hhs.gov](mailto:Angela.Tejeda@hhs.gov) or by calling 202–401–8297.

V. *Copies of the PTAC Charter and Meeting Material.* The Secretary’s Charter for the Physician-Focused Payment Model Technical Advisory Committee is available on the ASPE website at <https://aspe.hhs.gov/charter-physician-focused-payment-model-technical-advisory-committee>.

Additional material for this meeting can be found on the ASPE PTAC website. For updates and announcements, please use the link to subscribe to the ASPE PTAC email listserv.

Dated: January 31, 2018.

**John R. Graham,**

*Acting Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2018-02211 Filed 2-2-18; 8:45 am]

**BILLING CODE 4150-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Subcommittee.

*Date:* February 21–22, 2018.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Barbara A. Woynarowska, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 402-7172, [woynarowskab@nidk.nih.gov](mailto:woynarowskab@nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Digestive Diseases and Nutrition C Subcommittee.

*Date:* March 7–9, 2018.

*Time:* 6:00 p.m. to 10:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7017, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, [davila-bloomm@extra.nidk.nih.gov](mailto:davila-bloomm@extra.nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes,

Endocrinology and Metabolic Diseases B Subcommittee.

*Date:* March 7–9, 2018.

*Time:* 8:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* John F. Connaughton, Ph.D., Chief, Scientific Review Branch, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7797, [connaughtonj@extra.nidk.nih.gov](mailto:connaughtonj@extra.nidk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 31, 2018.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02253 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Data Archives for the BRAIN Initiative (R24) and Standards To Define Experiments Related to the BRAIN Initiative (R24).

*Date:* February 26, 2018.

*Time:* 12:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of

Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, [charlesvi@mail.nih.gov](mailto:charlesvi@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Clinical Trial and K Awards Review Meeting.

*Date:* February 27, 2018.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, [dsommers@mail.nih.gov](mailto:dsommers@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Integration and Analysis of BRAIN Initiative Data (R24).

*Date:* February 28, 2018

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, [charlesvi@mail.nih.gov](mailto:charlesvi@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 31, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02251 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 13, 2018, 4:00 p.m. to March 14, 2018, 5:00 p.m., Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852 which was published in the **Federal Register** on January 11, 2018, 83 FR 1378.

This meeting notice is amended to change the meeting name from “TEP-1: Development of Software Tools for Post Radiation Therapy Surveillance” to

“TEP-1: Software Tools for Post Radiation Therapy Surveillance”. The meeting location has been changed to the Hilton Washington DC/Rockville, Regency Room, 1750 Rockville Pike, Rockville, MD 20852. The meeting is closed to the public.

Dated: January 30, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy,*

[FR Doc. 2018-02155 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; SERV Conflicts.

*Date:* February 28, 2018.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892-9606, 301-443-9699, [bursteinme@mail.nih.gov](mailto:bursteinme@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Suicide Prevention Secondary Data Analyses.

*Date:* March 1, 2018.

*Time:* 1:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of

Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, [dsommers@mail.nih.gov](mailto:dsommers@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 31, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy,*

[FR Doc. 2018-02252 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Immunology Integrated Review Group; Cellular and Molecular Immunology—A Study Section.

*Date:* February 22–23, 2018.

*Time:* 8:30 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Mission Valley, 8757 Rio San Diego Drive, San Diego, CA 92108.

*Contact Person:* David B. Winter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301-435-1152, [dwinter@mail.nih.gov](mailto:dwinter@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR17-031: Role of Age-Associated Metabolic Changes in Alzheimer's Disease.

*Date:* February 22, 2018.

*Time:* 3:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC7846, Bethesda, MD 20892, (301) 435-1021, [rovescall@mail.nih.gov](mailto:rovescall@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Immune Mechanism.

*Date:* February 23, 2018.

*Time:* 1:00 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* San Diego Marriott Mission Valley, 8757 Rio San Diego Drive, San Diego, CA.

*Contact Person:* Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301-495-1506, [jakesse@mail.nih.gov](mailto:jakesse@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Investigations on Primary Immunodeficiency Diseases.

*Date:* February 27, 2018.

*Time:* 1:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301-435-1230, [jh377p@nih.gov](mailto:jh377p@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: BTSS and SAT.

*Date:* March 2, 2018.

*Time:* 12:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-237-9870, [xuguofen@csr.nih.gov](mailto:xuguofen@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Societal and Ethical Issues in Research.

*Date:* March 2, 2018.

*Time:* 12:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Gabriel B. Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435-3562, [fosug@csr.nih.gov](mailto:fosug@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

*Date:* March 5–6, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 2620 Hotel Fisherman's Wharf, 2620 Jones Street, San Francisco, CA 94133.

*Contact Person:* Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5211, Bethesda, MD 20892, 301-760-8207, [schauwecker@csr.nih.gov](mailto:schauwecker@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Neuro/Psychopathology, Lifespan Development, and STEM Education.

*Date:* March 5, 2018.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Elia E. Femia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3108, Bethesda, MD 20892, 301-827-7189, [femiaee@csr.nih.gov](mailto:femiaee@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Immune System Plasticity in Dental, Oral, and Craniofacial Diseases.

*Date:* March 5, 2018.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, [liuyh@csr.nih.gov](mailto:liuyh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: GI Physiology and Pathology.

*Date:* March 5, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Meenakshisundar Ananthanarayanan, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, Bethesda, MD 20892, 301-827-6281, [meena.ananthanarayanan@nih.gov](mailto:meena.ananthanarayanan@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Pilot Clinical Trials for The Spectrum of Alzheimer's Disease.

*Date:* March 5, 2018.

*Time:* 1:00 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Wind Cowles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3172, Bethesda, MD 20892, 301-437-7872, [cowleshw@csr.nih.gov](mailto:cowleshw@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 30, 2018.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02154 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Integrative Nutrition and Metabolic Processes Study Section, February 8, 2018, 8:00 a.m. to February 9, 2018, 1:00 p.m., Westin Grand, 2350 M Street NW, Washington, DC 20037 which was published in the **Federal Register** on January 05, 2018, 83 FR 682.

The meeting will be held on February 7, 2018, 5:00 p.m. and end on February 8, 2018, 6:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: January 30, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02151 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular and Cellular Endocrinology Study Section, February 8, 2018, 8:00 a.m. to February 9, 2018, 5:00 p.m., Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202 which was published in the **Federal Register** on January 19, 2018, 83 FR PG 2806.

This meeting will be held on February 7, 2018 at 5:30 p.m. and end February 8, 2018 8:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: January 30, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02152 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, TEP-8: Non-Mouse Reagents for Novel Therapeutics.

*Date:* February 23, 2018.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Bethesda, MD 20892-9750, 240-276-6343, [schweinfestcw@mail.nih.gov](mailto:schweinfestcw@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; TEP-11: Cancer Imaging Tools.

*Date:* March 8, 2018.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Eduardo E. Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Bethesda, MD 20892-9750, 240-276-7975, [chufanee@mail.nih.gov](mailto:chufanee@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; TEP-10: Immunoassay Development.

*Date:* March 15, 2018.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 2W030, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Yasuko Furumoto, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609, Medical Center Drive, Room 7W424, Bethesda, MD 20892-9750, 240-276-5287, [yasuko.furumoto@nih.gov](mailto:yasuko.furumoto@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; SEP-4; NCI Clinical and Translational Exploratory/Developmental Studies.

*Date:* April 24, 2018.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609, Medical Center Drive, Room 7W246, Bethesda, MD 20892-9750, 240-276-5460, [jfang@mail.nih.gov](mailto:jfang@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; TEP-5.

*Date:* April 26, 2018.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Reed A. Graves, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Bethesda, MD 20892-9750, 240-276-6384, [gravesr@mail.nih.gov](mailto:gravesr@mail.nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 30, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02156 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, February 13, 2018, 1:00 p.m. to February 13, 2018, 4:00 p.m.,

National Cancer Institute Shady Grove, Shady Grove, 9609 Medical Center Drive, TE 406, Rockville, MD 20850 which was published in the **Federal Register** on January 22, 2018, 83 FR 3003.

The meeting notice is being amended to change the meeting times for the open and closed sessions. The open session will be held from 1:00 p.m. to 3:10 p.m. The closed session will be held from 3:25 p.m. to 4:25 p.m. The meeting is partially closed to the public.

Dated: January 31, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02249 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Initial Review Group, Clinical, Treatment and Sub Services Research Review Subcommittee.

*Date:* March 23, 2018.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Level Conference Room 508, Bethesda, MD 20892.

*Contact Person:* Ranga V. Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451-2067, [srinivar@mail.nih.gov](mailto:srinivar@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National

Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: January 30, 2018.

**Melanie J. Pantoja,**

*Program Analyst Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02157 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Advisory Council.

*Date:* February 6, 2018.

*Open:* 8:30 a.m. to 11:30 a.m.

*Agenda:* To discuss program policies and issues.

*Place:* National Institutes of Health, Building 35A, Porter Building, 35A Convent Drive, Room 640, Bethesda, MD 20892.

*Closed:* 11:30 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 35A, Porter Building, 35A Convent Drive, Room 640, Bethesda, MD 20892.

*Contact Person:* Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, 301-435-0260 [moen@mail.nih.gov](mailto:moen@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: [www.nhlbi.nih.gov/meetings/nhlbac/index.htm](http://www.nhlbi.nih.gov/meetings/nhlbac/index.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 31, 2018.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02214 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Environmental Health Sciences; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Advisory Environmental Health Sciences Council, February 12, 2018, 8:30 a.m. to February 13, 2018, 10:30 a.m., National Institute of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709, which was published in the **Federal Register** on January 10, 2018, 83 FR 1265.

Due to the government operating under the strong possibility of the current Continuing Resolution ending before the original scheduled Council date, it would be difficult to reschedule the grant review within the given Council round. The institute made the decision to hold an abbreviated Closed session of Council via teleconference on Wednesday, February 7, 2018, 2:00 p.m. They were counseled to post this

information on their IC website. This meeting is closed to the public.

The open session of the National Advisory Environmental Health Sciences Council will be held as originally scheduled on February 12, 2018, 8:30 a.m. to 6:00 p.m. at the National Institute of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. This meeting is open to the public.

Dated: January 30, 2018.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02183 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies.

*Date:* February 22, 2018.

*Time:* 2:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-8886, [sanoviche@mail.nih.gov](mailto:sanoviche@mail.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-17-006: Center for Identification and Study of Individuals with Atypical Diabetes Mellitus (U54).

*Date:* March 1, 2018.

*Time:* 11:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-7682, [campd@extra.nidk.nih.gov](mailto:campd@extra.nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; CRIC Limited Competition.

*Date:* March 9, 2018.

*Time:* 1:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301-496-9010, [hoffertj@nidk.nih.gov](mailto:hoffertj@nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-16-127: NIDDK Program Projects (P01).

*Date:* March 13, 2018.

*Time:* 11:30 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidk.nih.gov](mailto:jerkinsa@nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Information Network Coordinating Unit.

*Date:* March 14, 2018.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, [tathamt@mail.nih.gov](mailto:tathamt@mail.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2).

*Date:* March 20, 2018.

*Time:* 11:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301-496-9010, [hoffertj@nidk.nih.gov](mailto:hoffertj@nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-17-005: George M. O'Brien Kidney Research Core Centers (P30).

*Date:* March 26-27, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidk.nih.gov](mailto:jerkinsa@nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-16-005: Identification of Mechanisms Mediating the Effects of Sleep on Diabetes-Related Metabolism in Humans (R01).

*Date:* March 30, 2018.

*Time:* 11:30 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidk.nih.gov](mailto:jerkinsa@nidk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 31, 2018.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02250 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Immunology Integrated Review Group; Immunity and Host Defense Study Section.

*Date:* February 22-23, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

*Contact Person:* Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301-435-1506, [jakesse@mail.nih.gov](mailto:jakesse@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-16-116: Bioengineering Research Partnerships (U01).

*Date:* February 26, 2018.

*Time:* 3:00 p.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Songtao Liu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, Bethesda, MD 20817, 301-435-3578, [songtao.liu@nih.gov](mailto:songtao.liu@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 14-166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

*Date:* February 27, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Songtao Liu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, Bethesda, MD 20817, 301-435-3578, [songtao.liu@nih.gov](mailto:songtao.liu@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Psychosocial Risks and Disease Prevention.

*Date:* March 2, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, 301-594-3292, [niw@csr.nih.gov](mailto:niw@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 30, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02153 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

*Date:* February 19-20, 2018.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

*Contact Person:* Denise R. Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301-435-0198, [shawdeni@csr.nih.gov](mailto:shawdeni@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Par Panel: Academic-Industrial Partnerships Research for Cancer Diagnosis and Treatment.

*Date:* February 22-23, 2018.

*Time:* 9:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122,

MSC 7854, Bethesda, MD 20892, 301-237-9870, [xuguofen@csr.nih.gov](mailto:xuguofen@csr.nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Clinical Oncology Study Section.

*Date:* February 26, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Reston Hotel, 11810

Sunrise Valley Dr., Reston, VA 20191.

*Contact Person:* Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301-806-2515, [chatterm@csr.nih.gov](mailto:chatterm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Antimicrobial Drug development and resistance.

*Date:* February 27, 2018.

*Time:* 8:00 a.m. to 9:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

*Contact Person:* Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 3202, Bethesda, MD 20892, 301-827-7233, [susan.boyle-vavra@nih.gov](mailto:susan.boyle-vavra@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory.

*Date:* February 27–28, 2018.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, [barnasg@csr.nih.gov](mailto:barnasg@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Health Disparities in and Caregiving for Alzheimer's Disease.

*Date:* February 28, 2018.

*Time:* 8:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.

*Contact Person:* Gabriel B. Fosug, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435-3562, [fosug@csr.nih.gov](mailto:fosug@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Virology—A Study Section.

*Date:* February 28–March 1, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marines' Memorial Club & Hotel, 609 Sutter St., San Francisco, CA 94102.

*Contact Person:* Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301-496-6980, [izumikm@csr.nih.gov](mailto:izumikm@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.

*Date:* February 28–March 1, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

*Contact Person:* Meenakshisundar Ananthanarayanan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, Bethesda, MD 20817, 301-435-1234, [ananth.ananthanarayanan@nih.gov](mailto:ananth.ananthanarayanan@nih.gov).

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Behavioral Genetics and Epidemiology Study Section.

*Date:* February 28, 2018.

*Time:* 8:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.

*Contact Person:* Suzanne J. Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301-435-1712, [ryansj@csr.nih.gov](mailto:ryansj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-OD-17-002, CASEL, Center for Coordination of Analytics, Science, Enhancement and Logistics in Tobacco Regulatory Science (U54).

*Date:* February 28, 2018.

*Time:* 11:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301-408-9115, [bsokolov@csr.nih.gov](mailto:bsokolov@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-RM-17-018: Coordinating Center for the Undiagnosed Diseases Network (UDN) Phase II (U01).

*Date:* February 28, 2018.

*Time:* 11:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, 301-272-4865, [pyonkh2@csr.nih.gov](mailto:pyonkh2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Molecular Mechanisms of APOE in Alzheimer's Pathogenesis.

*Date:* February 28, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, [hamelinc@csr.nih.gov](mailto:hamelinc@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Acute brain injury and recovery.

*Date:* February 28, 2018.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892-7846, 301-435-1254, [yakovleva@csr.nih.gov](mailto:yakovleva@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-02150 Filed 2-2-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the combined meeting on February 15, 2018, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) four National Advisory Councils: The SAMHSA National Advisory Council (NAC), the Center for Mental Health Services NAC, the Center for Substance Abuse Prevention NAC, the Center for Substance Abuse Treatment NAC; and the two SAMHSA Advisory Committees: Advisory Committee for Women's Services (ACWS) and the Tribal Technical Advisory Committee (TTAC).

SAMHSA's National Advisory Councils were established to advise the

Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and SAMHSA's Center Directors concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under Section 501 of the Public Health Service Act, the ACWS is statutorily mandated to advise the SAMHSA Assistant Secretary for Mental Health and Substance Use and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the TTAC for working with Federally-recognized Tribes to enhance the government-to-government relationship, and honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; SAMHSA's priorities and updates by the Centers and Office Directors; a presentation on the Report to Congress on the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC); a presentation on SAMHSA's role in recent behavioral health responses to disasters; and a council discussion.

The meeting is open to the public and will be held at the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857. Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by February 8, 2018. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact by February 8, 2018. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone and web conferencing will be available. To attend on site: Obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: <http://nac.samhsa.gov/Registration/>

[meetingsRegistration.aspx](http://nac.samhsa.gov/Registration/meetingsRegistration.aspx), or communicate with SAMHSA's Committee Management Officer, CDR Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at <http://www.samhsa.gov/about-us/advisory-councils/> or by contacting CDR Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website, <http://nac.samhsa.gov/>, or by contacting CDR Castillo.

**Council Names:**

Substance Abuse and Mental Health Services Administration National Advisory Council  
Center for Mental Health Services National Advisory Council  
Center for Substance Abuse Prevention National Advisory Council  
Center for Substance Abuse Treatment National Advisory Council  
Advisory Committee for Women's Services Tribal Technical Advisory Committee

**Date/Time/Type:** February 15, 2018, 9:00 a.m. to 4:25 p.m. EDT, Open.

**Place:** Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

**Contact:** CDR Carlos Castillo, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, Room 18E77A, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-2787, Email: [carlos.castillo@samhsa.hhs.gov](mailto:carlos.castillo@samhsa.hhs.gov).

**Carlos Castillo,**

Committee Management Officer, SAMHSA.

[FR Doc. 2018-02172 Filed 2-2-18; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the meeting on February 16, 2018, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Advisory Council (SAMHSA NAC).

The SAMHSA NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA, to

improve the provision of treatments and related services to individuals with respect to substance use and to improve prevention services, promote mental health, and protect legal rights of individuals with mental illness and individuals who are substance users.

The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; updates from the Department of Health and Human Services' Operating Divisions; updates from the ex-officio members, and a council discussion.

The meeting is open to the public and will be held at the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857. Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by February 8, 2018. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person by February 8, 2017. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone. To attend on site: obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx>, or communicate with SAMHSA's Committee Management Officer, CDR Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at <http://www.samhsa.gov/about-us/advisory-councils/> or by contacting CDR Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website, <http://nac.samhsa.gov/>, or by contacting CDR Castillo.

**Council Name:** Substance Abuse and Mental Health Services Administration National Advisory Council.

**Date/Time/Type:** February 16, 2018, 9:00 a.m. to 3:45 p.m. EDT, Open.

**Place:** Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

**Contact:** CDR Carlos Castillo, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, Room

18E77A, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-2787, Email: [carlos.castillo@samhsa.hhs.gov](mailto:carlos.castillo@samhsa.hhs.gov).

**Carlos Castillo,**

*Committee Management Officer, SAMHSA.*

[FR Doc. 2018-02173 Filed 2-2-18; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Customs and Border Protection**

**Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determinations.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued 11 final determinations concerning the country of origin of certain pharmaceutical products. Based upon the facts presented, CBP has concluded that the country of origin of the Rosuvastatin Calcium Tablets, Levofloxacin Tablets, Levetiracetam Tablets, Metoprolol Tartrate Tablets, Gabapentin Capsules, Carvedilol Tablets, Paroxetine Hydrochloride Tablets, Entecavir Tablets, Montelukast Sodium Tablets, Simvastatin Tablets, Donepezil Hydrochloride Tablets is India for purposes of U.S. Government procurement.

**DATES:** These final determinations were issued on January 30, 2018. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of these final determinations within March 7, 2018.

**FOR FURTHER INFORMATION CONTACT:** Elif Eroglu, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325-0277.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on January 30, 2018 CBP issued 11 final determinations concerning the country of origin of certain pharmaceutical products, which may be offered to the U.S. Government under an undesignated government procurement contract pursuant to subpart B of part 177, CBP Regulations (19 CFR part 177, subpart B). These final

determinations (H289700, H289701, H289702, H289704, H289706, H289710, H289711, H289712, H289713, H289714, and H289715), were issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determinations, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is India, the country where the active pharmaceutical ingredient was produced.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: January 30, 2018.

**Alice A. Kipel,**

*Executive Director, Regulations and Rulings, Office of Trade.*

**HQ H289700**

**January 30, 2018**

**OT:RR:CTF:** VS H289700 EE

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Rosuvastatin Calcium tablets  
Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>1</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Rosuvastatin Calcium

<sup>1</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Rosuvastatin Calcium tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Rosuvastatin Calcium tablets, members of a family of statin drugs prescribed for the reduction of cholesterol and triglyceride levels and prevention of heart attacks and strokes.

You state that Acetris procures the Rosuvastatin Calcium tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Rosuvastatin Calcium tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Rosuvastatin Calcium tablets is Rosuvastatin Calcium, which Aurolife sources from company X in India.

You state that the Rosuvastatin Calcium tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with several inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Rosuvastatin employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, and 40 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Rosuvastatin Calcium tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material  | Country                 |
|---|-------------------------|
| Rosuvastatin Calcium .....  | India                   |
| Lactose Monohydrate (Super Tab 30GR) USP-NF .....   | Country A               |
| Dibasic Calcium Phosphate, Anhydrous USP (Fujicalin SG) .....                                       | Country B               |
| Microcrystalline Cellulose USNF (Avicel PH-102)/Microcrystalline Cellulose USNF (Pharmel 102) ..... | United States/Country C |
| Crospovidone USNF (Polyplasdone XL-10) .....  | United States           |
| Magnesium Stearate NF Hyqual Veg Source #2257 .....   | United States           |
| Opady II Pink 31K84972 .....  | United States           |

The processing that occurs in the United States includes the following:

- Microcrystalline cellulose, lactose monohydrate, and dibasic calcium phosphate anhydrous are added to the Rosuvastatin Calcium API as adjuvant to improve the bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Crestor®) for therapeutic equivalency. These four excipients are blended according to a set protocol and blending times to ensure proper mixing. Dibasic Calcium Phosphate anhydrous is a key ingredient, addition of which results in a drug product with a higher pH than the API, preventing the instability, variable potency and formation of hazardous degradation byproducts that otherwise are present in the API, significantly enhancing the stability of the finished product.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, different coloring agents and film coating are added to give each strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.

You submitted product labels for the Rosuvastatin Calcium tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Rosuvastatin Calcium. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Rosuvastatin Calcium tablets.

#### ISSUE:

What is the country of origin of the Rosuvastatin Calcium tablets for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when

combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Rosuvastatin Calcium tablets, but prohibits

that same NDC from being associated with any API, such as Rosuvastatin Calcium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Rosuvastatin Calcium tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Rosuvastatin Calcium is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Rosuvastatin Calcium degrades so as to both reduce potency and create hazardous byproducts. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug with established potency, that meets all requirements for levels of impurity, including those produced as harmful degradation byproducts, and can be safely administered for the treatment of a human disease or condition.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Rosuvastatin Calcium, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Rosuvastatin Calcium tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Rosuvastatin Calcium tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48

C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Rosuvastatin Calcium tablets partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Rosuvastatin Calcium tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the **Federal Register**, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the **Federal Register** notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

**HQ H289701**

**January 30, 2018**

**OT:RR:CTF:VS** H289701 EE

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Levofloxacin tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")<sup>2</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Levofloxacin tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Levofloxacin tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Levofloxacin tablets, which are a fluoroquinolone antibacterial used to treat mild, moderate, and severe infections.

You state that Acetris procures the Levofloxacin tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Levofloxacin tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Levofloxacin tablets is Levofloxacin, which Aurolife sources from company X in India.

You state that the Levofloxacin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Levofloxacin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (250 mg, 500 mg, and 750 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Levofloxacin tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material  | Country |
|---|---------|
| Levofloxacin USP .....                                | India   |
| Croscarmellose Sodium USNF .....                      | USA     |
| Microcrystalline Cellulose USNF (Avicel PH 101) ..... | USA     |
| Hypromellose USP .....                                | USA     |
| Magnesium Stearate USNF .....                         | USA     |
| Opadry White 13B58802 IH .....                        | USA     |

<sup>2</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

| Material                        | Country |
|---------------------------------|---------|
| Opadry Orange 13B53926 IH ..... | USA     |
| Opadry Pink 13B84503 IH .....   | USA     |

The processing that occurs in the United States includes the following:

- Croscarmellose sodium is added as a disintegrant to provide easy dispersion of the tablet when engulfed by the patient which indirectly enhances the drug release process and bioavailability/absorption leading to pharmacokinetic profiles equivalent to the brand product (Levaquin®) for therapeutic equivalency.

- Microcrystalline cellulose is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Hypromellose is added as a binder to aid formation of flowable granules during manufacturing thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Film coating is performed using polymers which imparts a protective barrier for the drug and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of maintaining the overall integrity of the quality attributes and minimizing the formation of impurities thereby transforming it into a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Levofloxacin tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Levofloxacin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Levofloxacin tablets.

#### ISSUE:

What is the country of origin of the Levofloxacin tablets for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the

growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The

API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Levofloxacin tablets, but prohibits that same NDC from being associated with any API, such as Levofloxacin, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Levofloxacin tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Levofloxacin is intended only for use by producers for further processing or for research since it is unstable and not fit

for medical use and may not be sold to consumers. Additionally, you state that Levofloxacin exhibits poor flow properties, undergoes oxidative degradation, and has a bitter taste. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Levofloxacin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Levofloxacin tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Levofloxacin tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Levofloxacin tablets partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Levofloxacin tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

**HQ H289702**

**January 30, 2018**

**OT:RR:CTF:VS** H289702 EE

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Levetiracetam tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")<sup>3</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Levetiracetam tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Levetiracetam tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Levetiracetam tablets which are anti-epileptic medications indicated in treatment of partial onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures.

You state that Acetris procures the Levetiracetam tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Levetiracetam tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Levetiracetam tablets is Levetiracetam, which Aurolife sources from company X in India.

You state that the Levetiracetam tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Levetiracetam tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (250 mg, 500 mg, 750 mg, and 1000 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Levetiracetam tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                                | Country   |
|---|-----------|
| Levetiracetam USP .....                 | India     |
| Corn Starch USNF (Maize Starch B) ..... | Country A |
| Povidone USP (Kollidon 30) .....        | USA       |
| Colloidal Silicon Dioxide USNF .....    | USA       |
| Talc USP .....                          | USA       |
| Magnesium Stearate USNF .....           | USA       |
| Opadry Blue OY-S-30913 .....            | USA       |
| Opadry Yellow 05F82840 .....            | USA       |
| Opadry Orange OY-S-33016 .....          | USA       |
| Opadry White Y-1-7000 .....             | USA       |

<sup>3</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

The processing that occurs in the United States includes the following:

- Corn starch is added as a bulking agent for better manufacturability and to have a suitable tablet weight so that the patient can easily take the medication. Corn starch is mixed with the API, enhancing that the compressibility of the API, so that the product can be easily administered.
- Povidone is added as a binder to aid formation of flowable granules during manufacturing, thereby achieving the uniformity of the drug leading to therapeutic efficacy.
- Talc and Colloidal silicon dioxide are added to create a gliding property in the blend particles and to provide a lubrication effect during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.
- Coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed, using polymers, which imparts a protective barrier to each strength of the drug and to mask the taste.
- Finally, the tablets are packed into suitable containers which maintain the overall integrity of the quality attributes, thereby producing a more stable drug product whose therapeutic effectiveness is sustainable.

You submitted product labels for the Levetiracetam tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Levetiracetam. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make final Levetiracetam tablets.

#### ISSUE:

What is the country of origin of the Levetiracetam tablets for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use

distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical

properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Levetiracetam tablets, but prohibits that same NDC from being associated with any API, such as Levetiracetam, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Levetiracetam tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API has a bitter taste and poor compressibility properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product that achieves the targeted disintegration and dissolution, is more suitable and stable, and possesses the desired physicochemical properties.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Levetiracetam, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do

not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Levetiracetam tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Levetiracetam tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Levetiracetam tablets partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Levetiracetam tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review

of this final determination before the Court of International Trade.

Sincerely,  
 Alice A. Kipel  
 Executive Director  
 Regulations and Rulings  
 Office of Trade  
 HQ H289704

**January 30, 2018**

**OT:RR:CTF:VS** H289704 EE  
**CATEGORY:** Origin

Stephen E. Ruscus  
 Morgan, Lewis & Bockius LLP  
 1111 Pennsylvania Avenue, NW  
 Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Subpart B, Part 177. CBP Regulations; Metoprolol Tartrate tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>4</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Metoprolol Tartrate tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Metoprolol Tartrate tablets. You state that Acetris is a

generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Metoprolol Tartrate tablets, which are used in the treatment of hypertension, angina pectoris and myocardial infarction.

You state that Acetris procures the Metoprolol Tartrate tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Metoprolol Tartrate tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Metoprolol Tartrate tablets is Metoprolol Tartrate, which Aurolife sources from company X in India.

You state that the Metoprolol Tartrate tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Metoprolol Tartrate tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (25 mg, 50 mg, and 100 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Metoprolol Tartrate tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                                | Country       |
|---|---------------|
| Metoprolol Tartrate USP .....           | India         |
| Microcrystalline Cellulose USNF .....   | Country A/USA |
| Corn Starch USNF (Maize Starch B) ..... | Country B     |
| Sodium Starch Glycolate USNF .....      | Country C     |
| Colloidal Silicon Dioxide USNF .....    | USA           |
| Sodium Lauryl Sulfate USNF .....        | Country D     |
| Talc USNF .....                         | USA           |
| Magnesium Stearate USNF .....           | USA           |
| Opadry White 13B58867 .....             | USA           |
| Opadry Pink 13B54175 .....              | USA           |
| Opadry Blue 13B50500 .....              | USA           |

The processing that occurs in the United States includes the following:

- Microcrystalline cellulose and corn starch are added as bulking agents for better

manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents which alters the physical form of the

API such that the compressibility of the API is enhanced and the product can be easily administered.

<sup>4</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

- Sodium starch glycolate is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which indirectly enhances the drug release process and bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Lopressor®) for therapeutic equivalency.

- Talc and colloidal silicon dioxide are added to create a gliding property in the blend particles, contributing to the unit-to-unit uniformity of the drug during the manufacturing process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Sodium Lauryl Sulfate is added as a wetting agent to enhance the solubilization process and bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product for therapeutic equivalency.

- Coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each tablet strength and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of impurity, transforming it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Metoprolol Tartrate tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Metoprolol Tartrate. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Metoprolol Tartrate tablets.

#### ISSUE:

What is the country of origin of the Metoprolol Tartrate tablets for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or

instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change

in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Metoprolol Tartrate tablets, but prohibits that same NDC from being associated with any API, such as Metoprolol Tartrate, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Metoprolol Tartrate tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Metoprolol Tartrate is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the Metoprolol Tartrate degrades under hydrolysis and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API’s properties and make it into a stable drug product with the desired pharmacokinetics, therapeutic efficacy and physicochemical properties.

This office consulted with CBP’s Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Metoprolol Tartrate, retains its chemical and physical properties upon processing in the

United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Metoprolol Tartrate tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Metoprolol Tartrate tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Metoprolol Tartrate tablets partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Metoprolol Tartrate tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30

days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,  
Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

**HQ H289706**

**January 30, 2018**

**OT:RR:CTF:VS H289706 EE**  
**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177. CBP Regulations; Gabapentin Capsules  
Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”)<sup>5</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Gabapentin capsules. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Gabapentin capsules. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Gabapentin capsules, which are used for the management and/or treatment of postherpetic neuralgia in adults and partial onset seizures.

You state that Acetris procures the Gabapentin capsules from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Gabapentin capsules supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Gabapentin capsules is Gabapentin, which Aurolife sources from company X in India.

You state that the Gabapentin capsules supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Gabapentin capsules employs processes that convert these ingredients into finished, medically effective dosage capsules (100 mg, 300 mg, and 400 mg capsules). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Gabapentin capsules occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material  | Country           |
|---|-------------------|
| Gabapentin USP .....  | India             |
| Corn Starch USNF .....  | Country A         |
| Talc USP .....  | USA               |
| White/White size ‘3’ Capsule shell imprinted with ‘D’ on white cap and ‘02’ on white body .....     | Country B/USA/USA |
| Yellow/Yellow size ‘1’ Capsule shell imprinted with ‘D’ on yellow cap and ‘03’ on yellow body ..... | Country C/USA/USA |
| Orange/Orange size ‘0’ Capsule shell imprinted with ‘D’ on Orange cap and ‘04’ on Orange body ..... | Country D/USA/USA |

The processing that occurs in the United States includes the following:

- The API exhibits poor flow property whereby it will affect the manufacturability. Hence, the particle size is tailored to have good flowability during the manufacturing process so that there is no unit-to-unit

variability in the labeled quantity in each capsule.

- Corn starch is added as a bulking agent for better manufacturability and to have suitable fill weight so that the patient can easily take the medication. Corn starch is mixed with the gabapentin where the drug

particles get coated with the said excipient, enhancing stability.

- Talc is added to create a gliding property in the blend particles and also provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and

<sup>5</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, the blend is filled into hard gelatin shells to give each strength a distinct name and character. Encapsulation of the blend gives a protective barrier for each strength of the drug and masks the metallic taste of the drug particles.

You submitted product labels for the Gabapentin capsules. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Gabapentin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final the final Gabapentin capsules.

#### ISSUE:

What is the country of origin of the Gabapentin capsules for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part C.F.R. § 177 consistent with Federal Acquisition Regulations. See 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing.

A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor<sup>®</sup> (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary

dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Gabapentin capsules, but prohibits that same NDC from being associated with any API, such as Gabapentin, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Gabapentin capsule) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Gabapentin is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Gabapentin has a tendency to degrade and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API’s properties and make it into a stable drug product.

This office consulted with CBP’s Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Gabapentin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Gabapentin capsules would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Gabapentin capsules are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the

production of Gabapentin capsules partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Gabapentin capsules for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

**HQ H289710**

**January 30, 2018**

**OT:RR:CTF:VS H289710 EE**

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Carvedilol tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>6</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Carvedilol tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Carvedilol tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Carvedilol tablets, members of a family of drugs prescribed for treating mild to severe chronic heart failure, left ventricular dysfunction following myocardial infarction, and hypertension.

You state that Acetris procures the Carvedilol tablets from Aurolife Pharma LLC

(“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Carvedilol tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Carvedilol tablets is Carvedilol, which Aurolife sources from company X in India.

You state that the Carvedilol tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Carvedilol tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (3.125 mg, 6.25 mg, 12.5 mg, and 25 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Carvedilol tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                             | Country   |
|--------------------------------------|-----------|
| Carvedilol USP .....                 | India     |
| Lactose Monohydrate USNF .....       | Country A |
| Colloidal Silicon Dioxide USNF ..... | USA       |
| Crospovidone USNF .....              | USA       |
| Povidone USP .....                   | USA       |
| Sucrose USNF .....                   | USA       |
| Magnesium Stearate USNF .....        | USA       |
| Opadry White 12B18631 .....          | USA       |

The processing that occurs in the United States includes the following:

- Lactose monohydrate is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents to achieve uniformity of the API, so that the product can be easily administered.
- Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Coreg®) for therapeutic equivalency.
- Povidone and sucrose are added as binders to aid formation of flowable granules

during production, thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Colloidal silicon dioxide is added to create a gliding property in the blend particles, thereby contributing to the unit-to-unit uniformity of the drug during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.
- Coloring and film coating agents are added. Film coating is performed using

polymers which imparts a protective barrier for each tablet strength and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of impurities thereby producing a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Carvedilol tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Carvedilol. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Carvedilol tablets.

<sup>6</sup>Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

**ISSUE:**

What is the country of origin of the Carvedilol tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. See 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a

result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Carvedilol tablets, but prohibits that same NDC from being associated with any API, such as Carvedilol, that has not been demonstrated to be safe and effective and

cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Carvedilol tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API has poor flow quality and is susceptible to inadequate content uniformity. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Carvedilol, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Carvedilol tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Carvedilol tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Carvedilol tablets partially occurs in India, we do not find that they are manufactured in the United States.

**HOLDING:**

The country of origin of the Carvedilol tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30

days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,  
 Alice A. Kipel  
 Executive Director  
 Regulations and Rulings  
 Office of Trade

HQ H289711

January 30, 2018

OT:RR:CTF:VS H289711 EE

CATEGORY: Origin

Stephen E. Ruscus  
 Morgan, Lewis & Bockius LLP  
 1111 Pennsylvania Avenue, NW  
 Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Paroxetine Hydrochloride tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”)<sup>7</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Paroxetine

Hydrochloride tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Paroxetine Hydrochloride tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Paroxetine Hydrochloride tablets, which are psychotropic drugs used in the treatment of major depressive disorder, obsessive compulsive disorder, pain disorder, social anxiety disorder, generalized anxiety disorder, and post-traumatic stress disorder.

You state that Acetris procures the Paroxetine Hydrochloride tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product

manufacturer in the specialty and niche areas. Aurolife manufactures the Paroxetine Hydrochloride tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Paroxetine Hydrochloride tablets is Paroxetine Hydrochloride, which Aurolife sources from company X in India.

You state that the Paroxetine Hydrochloride tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Paroxetine Hydrochloride tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (10mg, 20mg, 30mg, and 40mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Paroxetine Hydrochloride tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                                  | Country   |
|---|-----------|
| Paroxetine Hydrochloride USP .....        | India     |
| Dibasic Calcium Phosphate Dihydrate ..... | USA       |
| Dibasic Calcium Phosphate Anhydrous ..... | Country A |
| Lactose Monohydrate USNF .....            | Country B |
| Sodium Starch Glycolate USNF .....        | Country C |
| Magnesium Stearate USNF .....             | USA       |
| Opadry yellow 13F52249 IH .....           | USA       |
| Opadry Pink 15B54027 IH .....             | USA       |
| Opadry Blue 12B50610 IH .....             | USA       |

The processing that occurs in the United States includes the following:

- Dibasic calcium phosphate dihydrate and dibasic calcium phosphate anhydrous are non-hygroscopic hydrophobic diluents added to the paroxetine hydrochloride to improve drug stability.
- Lactose monohydrate is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.
- Sodium starch glycolate is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Paxil®) for therapeutic equivalency.
- Magnesium stearate is added to create a hydrophobic environment around particles

which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agents and film coating are added to give each strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.
- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing discoloration, thereby permitting a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Paroxetine Hydrochloride tablets. You also

submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Paroxetine Hydrochloride. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the API and other ingredients into the final Paroxetine Hydrochloride tablets.

**ISSUE:**

What is the country of origin of the Paroxetine Hydrochloride tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the

<sup>7</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. See 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical

product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Paroxetine Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Paroxetine Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Paroxetine Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Paroxetine Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Paroxetine Hydrochloride experiences

degradation. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Paroxetine Hydrochloride, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Paroxetine Hydrochloride tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Paroxetine Hydrochloride tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Paroxetine Hydrochloride tablets partially occurs in India, we do not find that they are manufactured in the United States.

#### HOLDING:

The country of origin of the Paroxetine Hydrochloride tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

**HQ H289712**

**January 30, 2018**

**OT:RR:CTF:VS H289712 EE**

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Entecavir tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>8</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Entecavir tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Entecavir tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Entecavir tablets for treating the Hepatitis B virus (HBV).

You state that Acetris procures the Entecavir tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Entecavir tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP

compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Entecavir tablets is Entecavir, which Aurolife sources from company X in India.

You state that the Entecavir tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Entecavir tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (0.5 mg and 1 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Entecavir tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                                     | Country       |
|--|---------------|
| Entecavir USP .....                          | India         |
| Lactose Monohydrate USNF .....               | Country A     |
| Microcrystalline Cellulose PH 101 USNF ..... | USA/Country B |
| Crospovidone USNF (Kollidon CL) .....        | Country C     |
| Microcrystalline Cellulose PH 101 USNF ..... | USA/Country D |
| Magnesium Stearate USNF .....                | USA           |
| Aquarius BP18257 cool Vanilla IH .....       | USA           |

The processing that occurs in the United States includes the following:

- Lactose monohydrate and microcrystalline cellulose are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. These diluents also aid in achieving the desired uniformity with the help of processing steps like co-sifting.

- Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Baraclude<sup>®</sup>) for therapeutic equivalency.

- Magnesium stearate is added to create a hydrophobic environment around particles, which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Film coating agent is added to give each strength a distinct character. Film coating is performed using polymers which imparts a

protective barrier for each strength of the drug, making it appropriate for patient use.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes, thereby producing a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Entecavir tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Entecavir. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Entecavir tablets.

**ISSUE:**

What is the country of origin of the Entecavir tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or

practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or

<sup>8</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs

whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs

Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol

hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Entecavir tablets, but prohibits that same NDC from being associated with any API, such as Entecavir, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Entecavir tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is susceptible to inadequate content uniformity and undergoes oxidative degradation. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product that achieves the targeted disintegration and dissolution and exhibits appropriate physicochemical properties, the desired pharmacokinetics and therapeutic efficacy.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Entecavir, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Entecavir tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Entecavir tablets are “manufactured in the

United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Entecavir tablets partially occurs in India, we do not find that they are manufactured in the United States.

#### HOLDING:

The country of origin of the Entecavir tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

#### HQ H289713

January 30, 2018

OT:RR:CTF:VS H289713 EE

#### CATEGORY: Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Montelukast Sodium tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>9</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et*

<sup>9</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

seq.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Montelukast Sodium tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

**FACTS:**

The merchandise at issue are Montelukast Sodium tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has

its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Montelukast Sodium tablets, which are drugs prescribed for the prevention and/or treatment of asthma, bronchoconstriction and allergic rhinitis.

You state that Acetris procures the Montelukast Sodium tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Montelukast Sodium tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Montelukast Sodium tablets is Montelukast Sodium, which Aurolife sources from company Y in India.

You state that the Montelukast Sodium tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Montelukast Sodium tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (10 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Montelukast Sodium tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material                                       | Country   |
|--|-----------|
| Montelukast Sodium IH                          | India     |
| Lactose Monohydrate USNF                       | Country A |
| Microcrystalline Cellulose USNF (AVICEL PH101) | USA       |
| Croscarmellose Sodium USNF                     | USA       |
| Hydroxypropyl Cellulose USNF                   | USA       |
| Magnesium Stearate USNF                        | USA       |
| Opadry Yellow 20A82539 IH                      | USA       |

The processing that occurs in the United States includes the following:

- Lactose monohydrate, microcrystalline cellulose are added as bulking agents for better manufacturability so that the patient can easily take the medication.
- Hydroxypropyl cellulose is added as a binder to aid formation of flowable granules during manufacturing, thereby achieving the uniformity of the drug leading to therapeutic efficacy.
- Croscarmellose sodium is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Singular®) for therapeutic equivalency.
- Colloidal silicon dioxide is added to create a gliding property in the blend particles, thereby contributing to the unit-to-unit uniformity of the drug during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.
- Coloring agent and film coating are added to give an aesthetic appearance. Film coating is performed using polymers which imparts a protective barrier for the drug and to mask the taste.
- Finally, the tablets are packed into suitable containers which are capable of

retaining the overall integrity of the quality attributes and minimizing the formation of sulfoxide impurity, thereby transform it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Montelukast Sodium tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Montelukast Sodium. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Montelukast Sodium tablets.

**ISSUE:**

What is the country of origin of the Montelukast Sodium tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case

of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen*

Co., 27 C.C.P.A. 267 (1940); and, *National Juice Processing Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and

packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Montelukast Sodium tablets, but prohibits that same NDC from being associated with any API, such as Montelukast Sodium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Montelukast Sodium tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API degrades in potency, has poor flow qualities, and has a bitter taste. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Montelukast Sodium, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Montelukast Sodium tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Montelukast Sodium tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Montelukast Sodium tablets partially occurs in India, we do not find that they are manufactured in the United States.

#### HOLDING:

The country of origin of the Montelukast Sodium tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

#### HQ H289714

January 30, 2018

OT:RR:CTF:VS H289714 EE

CATEGORY: Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Simvastatin tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>10</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Simvastatin tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

#### FACTS:

The merchandise at issue are Simvastatin tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S.

<sup>10</sup>Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Simvastatin tablets, members of a family of statin drugs prescribed for lowering cholesterol and triglyceride levels and prevention of heart attacks and strokes.

You state that Acetris procures the Simvastatin tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Simvastatin tablets supplied to Acetris in a U.S. Food &

Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Simvastatin tablets is Simvastatin, which Aurolife sources from company X in India.

You state that the Simvastatin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients.

The production of Simvastatin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, 40 mg, and 80 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Simvastatin tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material  | Country       |
|---|---------------|
| Simvastatin USP .....                                 | India         |
| Ascorbic Acid USP (Micro powder) .....                | Country A     |
| Lactose Monohydrate USNF .....                        | Country B     |
| Microcrystalline Cellulose PH 101 USNF .....          | USA/Country C |
| Pregelatinized Starch USNF .....                      | USA           |
| Citric Acid Monohydrate USP (Extra Pure powder) ..... | Country D     |
| Butylated Hydroxy anisole USNF .....                  | USA           |
| Microcrystalline Cellulose PH 112 USNF .....          | Country E     |
| Magnesium Stearate USNF .....                         | USA           |
| Opadry yellow 20A52229 IH .....                       | USA           |
| Opadry Pink 20A54239 IH .....                         | USA           |
| Opadry Pink 20A54211 IH .....                         | USA           |
| Isopropyl Alcohol USP .....                           | USA           |

The processing that occurs in the United States includes the following:

- Butylated hydroxyanisole, ascorbic acid, and citric acid are added to the Simvastatin API to improve drug stability. BHA and ascorbic acid are included in the tablets as antioxidants. Citric acid is added because it has chelation properties with metal ions, which, in the absence of the citric acid, could catalyze the oxidation process and make the drug unstable. These three excipients are added according to a proprietary set of protocols with specified blending times to ensure proper mixing throughout the blend. Butylated hydroxyanisole, ascorbic acid, and citric acid are the key ingredients which create a protective environment for enhancing the stability of the finished product.

- Lactose monohydrate, microcrystalline cellulose are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Pregelatinized starch is added as a disintegrant to provide easy dispersion of the tablet when engulfed by the patient which indirectly enhances the drug release process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, different coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.

You submitted product labels for the Simvastatin tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Simvastatin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Simvastatin tablets.

**ISSUE:**

What is the country of origin of the Simvastatin tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products,

CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Simvastatin tablets, but prohibits that same NDC from being associated with any API,

such as Simvastatin, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Simvastatin tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Simvastatin is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API’s properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP’s Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Simvastatin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Simvastatin tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Simvastatin tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Simvastatin tablets partially occurs in India, we do not find that they are manufactured in the United States.

#### HOLDING:

The country of origin of the Simvastatin tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30

days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

HQ H289715

January 30, 2018

OT:RR:CTF:VS H289715 EE

CATEGORY: Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Donepezil Hydrochloride tablets  
Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>11</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Donepezil Hydrochloride tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

#### FACTS:

The merchandise at issue are Donepezil Hydrochloride tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Donepezil Hydrochloride tablets, members of a family of drugs prescribed for the treatment of dementia of the Alzheimer’s type.

You state that Acetris procures the Donepezil Hydrochloride tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche

<sup>11</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

areas. Aurolife manufactures the Donepezil Hydrochloride tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Donepezil Hydrochloride tablets is Donepezil Hydrochloride, which Aurolife sources from company X in India.

You state that the Donepezil Hydrochloride tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Donepezil Hydrochloride tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg and 10 mg tablets). You

state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Donepezil Hydrochloride tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

| Material  | Country   |
|---|-----------|
| Donepezil hydrochloride Hydrochloride monohydrate USP ..... | India     |
| Lactose Monohydrate USNF .....                              | Country A |
| Microcrystalline Cellulose USNF (UNITAB 102) .....          | USA       |
| Pregelatinized Starch .....                                 | USA       |
| Low substituted Hydroxypropyl Cellulose USNF .....          | Country B |
| Magnesium Stearate USNF .....                               | USA       |
| Opadry Yellow 03F82726 IH .....                             | USA       |
| Opadry White 03F180009 .....                                | USA       |

The processing that occurs in the United States includes the following:

- The particle size of the API is tailored to have a good flowability during the production process so that there is no unit-to-unit variability in the labeled quantity in each tablet.

- Lactose monohydrate and microcrystalline cellulose directly compressible grades are added as bulking agents for better flowability, manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Pregelatinized starch and low substituted hydroxypropyl cellulose are added as disintegrants to provide easy dispersion of the tablet when ingested by the patient, which enhances the release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Aricept®) for therapeutic equivalency.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agents and film coating are added to give an aesthetic appearance. Film coating is performed using polymers which imparts a protective barrier for the drug.

- Finally the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of oxidative impurity, thereby transforming it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Donepezil Hydrochloride tablets. You also submitted a shipping label and the Materials Safety Data Sheet (“MSDS”) for the API, Donepezil Hydrochloride. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Donepezil Hydrochloride tablets.

**ISSUE:**

What is the country of origin of the Donepezil Hydrochloride tablets for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of

commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in

the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Donepezil Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Donepezil Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Donepezil Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Donepezil Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is poisonous and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API’s properties and make it into a stable drug product.

This office consulted with CBP’s Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Donepezil Hydrochloride, retains its chemical and physical properties upon

processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Donepezil Hydrochloride tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Donepezil Hydrochloride tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Donepezil Hydrochloride tablets partially occurs in India, we do not find that they are manufactured in the United States.

#### **HOLDING:**

The country of origin of the Donepezil Hydrochloride tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade

[FR Doc. 2018–02245 Filed 2–2–18; 8:45 am]

**BILLING CODE 9111–14–P**

## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

#### **Notice of Issuance of Final Determination Concerning Certain Ethernet Switch Products**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of certain ethernet switch products known as Nyquist Ethernet Switches. Based upon the facts presented, CBP has concluded that the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on January 30, 2018. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within March 7, 2018.

**FOR FURTHER INFORMATION CONTACT:** Yuliya A. Gulis, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0042.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on January 30, 2018 pursuant to subpart B of part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain ethernet switch products known as Nyquist Ethernet Switches, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H282390, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the last substantial transformation took place in Mexico. Therefore, the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR

177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: January 30, 2018.

**Alice A. Kipel,**

*Executive Director, Regulations and Rulings,  
Office of Trade.*

**HQ H282390**

**January 30, 2018**

OT:RR:CTF:VS H282390 YAG

CATEGORY: Origin

Ms. Carolyn Muhlstein  
Senior Manager, Global Customs  
Cisco Systems, Inc.  
170 West Tasman Drive  
San Jose, CA 95134

RE: U.S. Government Procurement; Country of Origin of Ethernet Switch; Substantial Transformation

Dear Ms. Muhlstein:

This is in response to your letter, dated May 6, 2016, on behalf of Cisco Systems, Inc. ("Cisco"), requesting a final determination concerning the country of origin of Cisco's Nyquist Ethernet Switch ("NES"), pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 CFR § 177.21, *et seq.*). As a domestic importer of merchandise, Cisco is a party-at-interest within the meaning of 19 CFR § 177.22(d)(1) and is entitled to request this final determination. In addition, we have reviewed and grant the request for confidentiality pursuant to 19 CFR § 177.2(b)(7), with respect to certain information submitted.

**FACTS:**

Cisco plans to import the NES from Mexico. The NES is designed to interconnect devices on a computer network, while offering new capabilities, such as enabling new applications, differentiated security, dense wireless, and simplified and diverse network architecture. Each NES consists of one or more printed circuit board assemblies ("PCBA"), two power supplies, an uplink module, a protective metal housing, and ancillary devices to support additional features. The NES is configured with Cisco's configuration data. The configuration data programs the logic gates of the hardware components on the PCBA, which imparts physical changes to the patterns of interconnections in the hardware circuitry, defining the behavior of each component. The NES operates using Cisco's Polaris Operating System Software ("Polaris OS").

In China, PCBAs are manufactured using: application specific integrated circuit ("ASIC") components, which are assembled to final form in Korea incorporating materials from Taiwan and Japan in a process that takes between 12 and 25 weeks; central processing unit ("CPU") components from Taiwan; synchronous dynamic random access memory ("SDRAM") components from Taiwan or Korea; and, flash components from Korea and China. The PCBAs are tested to ensure that the PCBA components can properly interact with one another, and they are packaged and shipped to Mexico.

In Mexico, the following operations take place:

1. One or more PCBAs are installed into the NES chassis.
2. Two power supplies are installed in the NES chassis.
3. One uplink module is installed in the NES chassis.
4. Ancillary devices that support additional NES features are installed into the chassis.
5. A metal housing is added to complete the NES chassis assembly.
6. The power-on and bootloader initialization take place to activate the power system and fan modules of the NES, followed by the activation and preliminary testing of the CPU, ASIC, and ancillary devices.
7. The Polaris OS and configuration data developed in the United States are loaded onto a non-volatile flash memory, and then pushed out to the components of the PCBA.
8. The NES is tested to ensure the product functions as designed.

Cisco states that the Polaris OS and configuration data are downloaded onto the NES using in-circuit programming. According to Cisco, traditionally, each component of a PCBA (*e.g.*, ASICs) is completely programmed at or prior to assembly onto the PCBA; however, with in-circuit programming the hardware components are designed to be programmed after the PCBA is completely assembled. Cisco states that while the Polaris OS and configuration data are simultaneously downloaded onto the NES through the in-circuit programming, the Polaris OS and configuration data have different purposes and affect the NES differently and in sequence. Cisco explains that the configuration data does not operate on the hardware in the manner that the Polaris OS does. Rather, the configuration data completes the hardware programming, and the Polaris OS runs on the completed hardware.

According to Cisco, the PCBAs will have no commercial functionality when exported from China to Mexico because without the configuration data and the Polaris OS, the NES cannot function as intended. Cisco states that the NES will have large quantities of configurable elements, which require the configuration data to provide the firmware, modes and configuration settings, timing parameters, and physical properties for the components to function in the NES. Cisco states that the Polaris OS will provide I/O processor, route processor, and forwarding processor capabilities to the hardware, allowing the components to communicate with each other. Cisco notes that approximately 95 percent of the configuration data and 70 to 80 percent of the software code that will be loaded onto the NES in Mexico will be completely new and tailored based on customer needs and specifications.

**ISSUE:**

What is the country of origin of the NES for purposes of U.S. Government procurement?

**LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 CFR § 177.22(a). In order to determine whether a substantial transformation occurs when the components of various origins are assembled to form completed articles, CBP considers the totality of the circumstances and makes decisions on a case-by-case basis.

In *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that the programming of a foreign PROM ("Programmable Read-Only Memory" chip) in the United States substantially transformed the PROM into a U.S. article. In the United States, the programming bestowed upon each integrated circuit its electronic function, that is, its "memory" which could be retrieved. A distinct physical change was effected in the PROM by the opening or closing of the fuses, depending on the method of programming. The essence of the article, its interconnections or stored memory, was established by programming. *See also, Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982) (stating the substantial transformation issue is a "mixed question of technology and customs law").

Accordingly, the programming of a device that defines its use generally constitutes substantial transformation. *See* Headquarters Ruling ("HQ") HQ 735027, dated September 7, 1993 (programming blank media (EEPROM) with instructions that allow it to perform certain functions that prevent piracy of software constitutes a substantial transformation); *but see* HQ 734518, dated June 28, 1993 (motherboards are not substantially transformed by the implanting of the central processing unit on the board because, whereas in *Data General* use was being assigned to the PROM, the use of the motherboard had already been determined when the importer imported it).

Cisco argues that the country of origin of the NES will be Mexico because the final assembly of the NES and installation of the Polaris OS and configuration data onto the NES in Mexico will substantially transform the PCBA into the NES. While the configuration data is specific to the NES,

Cisco notes that the ASIC is not, and can be used in other Cisco products with different configuration data. Additionally, Cisco states that the Polaris OS allows the NES to switch and route packets, which is the critical functional element of the NES. Cisco states that the configuration data physically changes the electrical values of the logic gates present in the ASICs and other components, by connecting the gates in combinations that tell the components how to function and communicate within the system. Cisco argues that the configuration data installed on the NES should be distinguished from software installations because the configuration data completes the hardware programming, physically changing the hardware itself. Cisco states the software's incorporation onto the NES is different because it runs on the completed hardware as opposed to being a part of the hardware itself.

Cisco cites HQ 563012, dated May 4, 2004, in support of its position. In HQ 563012, CBP held that the PCBA and casing that were manufactured for a switch in China, were substantially transformed in the United States or Hong Kong, where U.S.-origin software was loaded, and the PCBA was further assembled with a power supply, fans, and an A/C filter of various origins to form the final fabric switch. CBP noted that in addition to the actual assembly, the configuration and software download operations performed in either Hong Kong or in the United States transformed the switch from a non-functional device into a fabric switch that was capable of performing various storage network functions.

Similar to the scenario in HQ 563012, where Hong Kong was found to be the origin, in this case, the major components of the NES, particularly the PCBA comprised of the ASIC, CPU, SDRAM, and flash components, will be manufactured in China, and then shipped to another country where the final assembly (adding the casing, power supply, uplink modules, and ancillary devices to the PCBA), software loading, configuration, and testing take place. Here, the other country is Mexico, which is different from the country where the U.S.-origin software is developed. While CBP has normally focused on where the origin of the software and where the programming took place, applying CBP's precedent in HQ 563012 to Cisco's manufacturing operations in Mexico, we find that the PCBAs from China will be substantially transformed by the final assembly, software loading, configuration, and testing operations in Mexico, and thus the country of origin for purposes of U.S. Government procurement will be Mexico.<sup>1</sup>

<sup>1</sup> See HQ H175415, dated October 4, 2011 (CBP held that imported Ethernet switches underwent a substantial transformation after U.S.-origin software was downloaded onto the devices' flash memory in the United States, which allowed the devices to function); see also HQ H052325, dated March 31, 2009 (holding that imported network devices underwent a substantial transformation in the United States after U.S.-origin software was downloaded onto the devices in the United States, which gave the devices their functionality); and, HQ H034843, dated May 5, 2009 (holding that Chinese USB flash drives underwent a substantial

#### HOLDING:

Based on the facts provided, the PCBAs from China will be substantially transformed into the NES by the processes that take place in Mexico. As such, the NES will be considered a product of Mexico for purposes of U.S. Government procurement.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel,  
Executive Director  
Regulations and Rulings  
Office of Trade

[FR Doc. 2018-02244 Filed 2-2-18; 8:45 am]

**BILLING CODE 9111-14-P**

#### INTERNATIONAL TRADE COMMISSION

[USITC SE-18-007]

#### Government in the Sunshine Act Meeting Notice

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** February 9, 2018 at 11:00 a.m.

**PLACE:** Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

**STATUS:** Open to the public.

#### MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
  2. Minutes.
  3. Ratification List.
  4. Vote in Inv. Nos. 701-TA-592 and 731-TA-1400 (Preliminary) (Plastic Decorative Ribbons from China). The Commission is currently scheduled to complete and file its determinations on February 12, 2018; views of the Commission are currently scheduled to be completed and filed on February 20, 2018.
  5. *Outstanding action jackets:* None.
- In accordance with Commission policy, subject matter listed above, not

transformation in Israel when Israeli-origin software was loaded onto the devices, which made the devices functional). CBP has also held that when software is programmed in one country, and loaded onto a switch in different countries, the process of loading the software is not a sufficient operation by itself to result in a substantial transformation. See HQ H241177, dated December 3, 2013; and, HQ H240199, dated March 10, 2015.

disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: January 31, 2018.

**William R. Bishop,**

*Supervisory Hearings and Information Officer.*

[FR Doc. 2018-02280 Filed 2-1-18; 11:15 am]

**BILLING CODE 7020-02-P**

#### INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1099]

#### Certain Graphics Processors and Products Containing the Same Institution of Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 29, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of ZiiLabs Inc., Ltd. of Bermuda. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain graphics processors and products containing the same by reason of infringement of certain claims of U.S. Patent No. 6,181,355 ("the '355 Patent"); U.S. Patent No. 6,900,800 ("the '800 Patent"); U.S. Patent No. 8,144,156 ("the '156 Patent"); and U.S. Patent No. 8,643,659 ("the '659 Patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

**ADDRESSES:** The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-

2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Katherine Hiner, the Office of the Secretary, Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

**SUPPLEMENTARY INFORMATION:**

**Authority:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

**Scope of Investigation:** Having considered the complaint, the U.S. International Trade Commission, on January 29, 2018, *ORDERED THAT*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation is instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain graphics processors and products containing the same by reason of infringement of one or more of claims 1-11 of the '355 Patent; claims 1, 2, 6, 7, and 11-19 of the '800 Patent; claims 1-16 of the '156 Patent; and claims 1-10 and 15-20 of the '659 Patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: ZiiLabs Inc., Ltd., Clarendon House, 2 Church Street, Hamilton, HM11, Bermuda.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

ASUSTeK Computer Inc., No. 15, Li-Te Road, Beitou District, Taipei 112, Taiwan

ASUS Computer International, 800 Corporate Way, Fremont, CA 94539

EVGA Corporation, 408 Saturn Street, Brea, CA 92821

Gigabyte Technology Co., Ltd., No. 6, Baoqiang Road, Xindian District, New Taipei City 231, Taiwan

G.B.T. Inc., 17358 Railroad Street, City of Industry, CA 91748

Micro-Star International Co., Ltd., No. 69, Lide Street, Zhonghe District, New Taipei City 235, Taiwan

MSI Computer Corp., 901 Canada Court, City of Industry, CA 91748

Nintendo Co., Ltd., 11-1 Hokotate-cho, Kamitoba, Minami-ku, Kyoto 601-8501, Japan

Nintendo of America Inc., 4600 150th Avenue NE, Redmond, WA 98052

Nvidia Corporation, 2788 San Tomas Expressway, Santa Clara, CA 95051

PNY Technologies Inc., 100 Jefferson Road, Parsippany, NJ 07054

Zotac International (MCO) Ltd., Rua de Pequin No. 202A-246, Macau Finance Centre, 16 Andar L, Macau, Macau

Zotac USA Inc., 1220 Highland Avenue, Suite 930, Duarte, CA 91009

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: January 30, 2018.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2018-02177 Filed 2-2-18; 8:45 am]

**BILLING CODE 7020-02-P**

**INTERNATIONAL TRADE COMMISSION**

[Investigation No. 337-TA-1036]

**Certain Magnetic Tape Cartridges and Components Thereof; Notice of Request for Statements on the Public Interest**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the presiding administrative law judge has issued a Final Initial Determination on Section 337 Violation and a Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, should the Commission find a violation, specifically a limited exclusion order ("LEO") against certain magnetic tape cartridges and components thereof, which are imported, sold for importation, and/or sold after importation by Respondents Fujifilm Holdings Corporation of Tokyo, Japan; Fujifilm Corporation of Tokyo, Japan; Fujifilm Holdings America Corporation of Valhalla, New York; and Fujifilm Recording Media U.S.A., Inc. of Bedford, Massachusetts (collectively "Fujifilm" or "Respondents"); and a cease and desist order ("CDO") against Respondents. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to Commission rules.

**FOR FURTHER INFORMATION CONTACT:**

Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2392. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>, and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the

Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** Section 337 of the Tariff Act of 1930 ("Section 337") provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4). In addition, members of the public are hereby invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on January 25, 2018. Comments should address whether issuance of the LEO and CDO in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the recommended orders are used in the United States;
- (ii) Identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;
- (iii) Identify like or directly competitive articles that complainants, their licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) Indicate whether complainants, complainants' licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) Explain how the LEO and CDO would impact consumers in the United States.

Written submissions from the public must be filed no later than by close of business on Thursday, March 1, 2018.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1036") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, [https://www.usitc.gov/secretary/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf)). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.  
Issued: January 30, 2018.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2018-02178 Filed 2-2-18; 8:45 am]

**BILLING CODE 7020-02-P**

## **INTERNATIONAL TRADE COMMISSION**

**[Investigation Nos. 701-TA-598-600 and 731-TA-1408-1410 (Preliminary)]**

### **Rubber Bands From China, Sri Lanka, and Thailand; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations**

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701-TA-598-600 and 731-TA-1408-1410 (Preliminary) pursuant to the Tariff Act of 1930 ("the Act") to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of rubber bands from China, Sri Lanka, and Thailand, provided for in subheading 4016.99.35 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Governments of China, Sri Lanka, and Thailand. Unless the Department of Commerce extends the time for initiation, the Commission must reach preliminary determinations in antidumping and countervailing duty investigations in 45 days, or in this case by March 16, 2018. The Commission's views must be transmitted to Commerce within five business days thereafter, or by March 23, 2018.

**DATES:** January 30, 2018.

**FOR FURTHER INFORMATION CONTACT:**

Mary Messer (202-205-3193) or Amanda Lawrence (202-205-3185), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

**SUPPLEMENTARY INFORMATION:**

*Background.*—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on January 30, 2018, by Alliance Rubber Co., Hot Springs, Arkansas.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B

(19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

**Participation in the investigations and public service list.**—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

**Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.**—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

**Conference.**—The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on February 20, 2018, at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Requests to appear at the conference should be emailed to [preliminaryconferences@usitc.gov](mailto:preliminaryconferences@usitc.gov) (DO NOT FILE ON EDIS) on or before February 15, 2018. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

**Written submissions.**—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before

February 23, 2018, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's website at <https://edis.usitc.gov>, elaborates upon the Commission's rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Certification.**—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: January 30, 2018.

**Lisa R. Barton,**  
Secretary to the Commission.

[FR Doc. 2018-02176 Filed 2-2-18; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731-TA-1353 and 1356 (Final)]

### Carbon and Certain Alloy Steel Wire Rod From South Africa and Ukraine; Supplemental Schedule for the Subject Investigations

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**APPLICABLE DATE:** January 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Douglas Corkran (202-205-3057), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

**SUPPLEMENTARY INFORMATION:** Effective September 5, 2017, the Commission established a general schedule for the conduct of the final phase of its investigations on carbon and certain alloy steel wire rod,<sup>1</sup> following preliminary determinations by the U.S. Department of Commerce ("Commerce") that imports of the subject wire rod were subsidized by the governments of Italy and Turkey. To date, Commerce has issued final affirmative determinations with respect to the subject wire rod from (1) Belarus, the Russian Federation, and the United Arab Emirates<sup>2</sup> and most recently (2) South Africa<sup>3</sup> and Ukraine.<sup>4</sup>

<sup>1</sup> *Wire Rod From Belarus, Italy, Korea, Russia, South Africa, Spain, Turkey, Ukraine, the United Arab Emirates, and the United Kingdom; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations*, 82 FR 44001, September 20, 2017.

<sup>2</sup> *Certain Carbon and Alloy Steel Wire Rod From Belarus, the Russian Federation, and the United Arab Emirates: Affirmative Final Determinations of Sales at Less Than Fair Value and Partial Affirmative Finding of Critical Circumstances*, 82 FR 56214, November 28, 2017.

<sup>3</sup> *Carbon and Alloy Steel Wire Rod From the Republic of South Africa: Affirmative Final Determination of Sales at Less Than Fair Value and Affirmative Finding of Critical Circumstances*, 83 FR 2141, January 16, 2018.

<sup>4</sup> *Carbon and Alloy Steel Wire Rod From Ukraine: Affirmative Final Determination of Sales at Less Than Fair Value*, 83 FR 2135, January 16, 2018.

The Commission, therefore, is issuing a supplemental schedule for its investigations on imports of carbon and certain alloy steel wire rod from South Africa and Ukraine.

The Commission's supplemental schedule is as follows: The deadline for filing supplemental party comments on Commerce's final determinations is February 2, 2018; the staff report in the final phase of these investigations will be placed in the nonpublic record on February 9, 2018; and a public version will be issued thereafter.

Supplemental party comments may address only Commerce's final determinations regarding of carbon and certain alloy steel wire rod from South Africa and Ukraine. These supplemental final comments may not contain new factual information and may not exceed five (5) pages in length.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: January 31, 2018.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2018-02233 Filed 2-2-18; 8:45 am]

**BILLING CODE 7020-02-P**

## JUDICIAL CONFERENCE OF THE UNITED STATES

### Meeting of the Judicial Conference Advisory Committee on Rules of Criminal Procedure

**AGENCY:** Judicial Conference of the United States, Advisory Committee on Rules of Criminal Procedure.

**ACTION:** Notice of open meeting.

**SUMMARY:** The Advisory Committee on Rules of Criminal Procedure will hold a meeting on April 24, 2018. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

**DATES:** April 24, 2018.

*Time:* 9:00 a.m. to 5:00 p.m.

**ADDRESSES:** Thurgood Marshall Federal Judiciary Building, Mechem Conference

Center, Administrative Office of the United States Courts, One Columbus Circle NE, Washington, DC 20544.

#### FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: January 30, 2018.

**Rebecca A. Womeldorf,**

*Rules Committee Secretary.*

[FR Doc. 2018-02179 Filed 2-2-18; 8:45 am]

**BILLING CODE 2210-55-P**

## JUDICIAL CONFERENCE OF THE UNITED STATES

### Meeting of the Judicial Conference Advisory Committee on Rules of Evidence

**AGENCY:** Advisory Committee on Rules of Evidence, Judicial Conference of the United States.

**ACTION:** Notice of open meeting.

**SUMMARY:** The Advisory Committee on Rules of Evidence will hold a meeting on April 27, 2018. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

**DATES:** April 27, 2018

*Time:* 9:00 a.m. to 5:00 p.m.

**ADDRESSES:** Thurgood Marshall Federal Judiciary Building, Mechem Conference Center, Administrative Office of the United States Courts, One Columbus Circle NE, Washington, DC 20544.

#### FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: January 30, 2018.

**Rebecca A. Womeldorf,**

*Rules Committee Secretary.*

[FR Doc. 2018-02180 Filed 2-2-18; 8:45 am]

**BILLING CODE 2210-55-P**

## DEPARTMENT OF JUSTICE

[OMB Number 1125-0003]

### Agency Information Collection Activities; Proposed Collection; Comments Requested; Fee Waiver Request

**AGENCY:** Executive Office for Immigration Review, Department of Justice.

**ACTION:** 30-day notice.

**SUMMARY:** The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted for an additional 30 days until March 7, 2018.

**FOR FURTHER INFORMATION CONTACT:** If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jean King, General Counsel, Executive Office for Immigration Review, U.S. Department of Justice, Suite 2600, 5107 Leesburg Pike, Falls Church, Virginia 22041; telephone: (703) 305-0470. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to [OIRA\\_submissions@omb.eop.gov](mailto:OIRA_submissions@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- Minimize the burden of the collection of information on those who are to respond, including through the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision and extension of a currently approved collection.

2. *The Title of the Form/Collection:* Fee Waiver Request.

3. *The agency form number:* Form EOIR-26A (OMB 1125-0003).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: An individual submitting an appeal or motion to the Board of Immigration Appeals. Other: Attorneys and qualified representatives representing an alien in immigration proceedings before EOIR. Abstract: The information on the fee waiver request form is used by the Board of Immigration Appeals to determine whether the requisite fee for a motion or appeal will be waived due to an individual's financial situation.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that there are 7,116 respondents, 7,116 annual responses, and that each response takes 1 hour to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* 7,116 annual burden hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: January 31, 2018.

**Melody D. Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2018-02192 Filed 2-2-18; 8:45 am]

**BILLING CODE 4410-30-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2018-0001]

### Sunshine Act Meeting Notice

**DATE:** Weeks of February 5, 12, 19, 26, March 5, 12, 2018.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

### Week of February 5, 2018

*Thursday, February 8, 2018*

9:00 a.m. Discussion of Potential Changes to the 10 CFR 2.206 Enforcement Petition Process (Public Meeting) (Contact: Doug Broaddus: 301-415-8124)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

### Week of February 12, 2018—Tentative

There are no meetings scheduled for the week of February 12, 2018.

### Week of February 19, 2018—Tentative

There are no meetings scheduled for the week of February 19, 2018.

### Week of February 26, 2018—Tentative

There are no meetings scheduled for the week of February 26, 2018.

### Week of March 5, 2018—Tentative

*Thursday, March 8, 2018*

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting) (Contact: Sophie Holiday: 301-415-7865)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

### Week of March 12, 2018—Tentative

There are no meetings scheduled for the week of March 12, 2018.

\* \* \* \* \*

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at [Denise.McGovern@nrc.gov](mailto:Denise.McGovern@nrc.gov).

\* \* \* \* \*

The NRC Commission Meeting Schedule can be found on the internet at: <http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

\* \* \* \* \*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301-287-0739, by videophone at 240-428-3217, or by email at [Kimberly.Meyer-Chambers@nrc.gov](mailto:Kimberly.Meyer-Chambers@nrc.gov). Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

\* \* \* \* \*

Members of the public may request to receive this information electronically. If you would like to be added to the

distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or email [Patricia.Jimenez@nrc.gov](mailto:Patricia.Jimenez@nrc.gov).

Dated: January 31, 2018.

**Denise L. McGovern,**

*Policy Coordinator, Office of the Secretary.*

[FR Doc. 2018-02274 Filed 2-1-18; 11:15 am]

**BILLING CODE 7590-01-P**

## PENSION BENEFIT GUARANTY CORPORATION

### OMB Approval of Information Collection; Missing Participants

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Notice of OMB approval of new information collection.

**SUMMARY:** The Office of Management and Budget has approved a new collection of information under the Pension Benefit Guaranty Corporation's regulations on Missing Participants.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Cibinic ([cibinic.stephanie@pbgc.gov](mailto:cibinic.stephanie@pbgc.gov)), Deputy Assistant General Counsel, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026; 202 326-4400, extension 6352. TTY/ASCII users may call the Federal relay service toll-free at 800-877-8339 and ask to be connected to 202-326-4400.

**SUPPLEMENTARY INFORMATION:** Pursuant to regulation under the Paperwork Reduction Act of 1995 (PRA) for information collections contained in a rulemaking, 5 CFR 1320.11(k), the Pension Benefit Guaranty Corporation is publishing this notice to inform the public that the Office of Management and Budget (OMB) has approved a new collection of information.

On December 22, 2017 (at 82 FR 60800), PBGC published a final rule amending its regulations on Missing Participants (29 CFR part 4050). This final rule expands PBGC's Missing Participants Program for terminated single-employer defined benefit pension plans covered by PBGC's insurance program to most defined contribution plans, multiemployer defined benefit pension plans, and small professional service defined benefit pension plans not covered by PBGC. The rule was effective on January 22, 2018, and applicable to plans that terminate on or after January 1, 2018.

PBGC submitted the new collection of information to OMB for review under

the PRA on December 22, 2017. On January 25, 2018, OMB approved the new collection of information through January 31, 2021, under OMB Control No. 1212-0069. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Issued in Washington DC.

**Stephanie Cibinic,**

*Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.*

[FR Doc. 2018-02201 Filed 2-2-18; 8:45 am]

**BILLING CODE 7709-02-P**

## OFFICE OF PERSONNEL MANAGEMENT

### Submission for Review: Designation of Beneficiary (FERS), Standard Form 3102

**AGENCY:** Office of Personnel Management.

**ACTION:** 30-Day notice and request for comments.

**SUMMARY:** The Retirement Operations, Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection, Designation of Beneficiary (FERS), Standard Form 3102.

**DATES:** Comments are encouraged and will be accepted until March 7, 2018.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316-L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to [Cyrus.Benson@opm.gov](mailto:Cyrus.Benson@opm.gov) or faxed to (202) 606-0910 or via telephone at (202) 606-4808.

**SUPPLEMENTARY INFORMATION:** As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206-0173) was

previously published in the **Federal Register** on April 13, 2017, at 82 FR 17890, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Standard Form 3102 is used by an employee or an annuitant covered under the Federal Employees Retirement System to designate a beneficiary to receive any lump sum due in the event of his/her death.

#### Analysis

*Agency:* Retirement Operations, Retirement Services, Office of Personnel Management.

*Title:* Designation of Beneficiary (FERS).

*OMB Number:* 3206-0173.

*Frequency:* On occasion.

*Affected Public:* Individual or Households.

*Number of Respondents:* 3,888.

*Estimated Time per Respondent:* 15 minutes.

*Total Burden Hours:* 972.

Office of Personnel Management.

**Kathleen M. McGettigan,**

*Acting Director.*

[FR Doc. 2018-02231 Filed 2-2-18; 8:45 am]

**BILLING CODE 6325-38-P**

## OFFICE OF SCIENCE AND TECHNOLOGY POLICY

### National Strategic Plan for Advanced Manufacturing

**AGENCY:** Office of Science and Technology Policy (OSTP).

**ACTION:** Notice of Request for Information.

**SUMMARY:** On behalf of the National Science and Technology Council, Committee on Technology, Subcommittee on Advanced Manufacturing, the Office of Science and Technology Policy (OSTP) requests input from all interested parties on the development of a National Strategic Plan for Advanced Manufacturing. Through this Request for Information (RFI), OSTP seeks input from the public on ways to improve government coordination and on long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including advanced manufacturing research and development that will create jobs, grow the economy across multiple industrial sectors, strengthen national security, and improve healthcare. The public input provided in response to this RFI will inform OSTP and NSTC as they work with Federal agencies and other stakeholders to develop the strategic plan.

**DATES:** Responses are due by March 7, 2018.

**ADDRESSES:** Responses should be submitted online at <https://www.nist.gov/oam/rfi-response> or via email to [amnpa@nist.gov](mailto:amnpa@nist.gov). Submissions via email should include "RFI Response: National Strategic Plan for Advanced Manufacturing" in the subject line of the message.

*Instructions:* Response to this RFI is voluntary. Respondents need not reply to all questions listed. For submissions via email, clearly indicate which questions are being answered. Email attachments will be accepted in plain text, Microsoft Word, or Adobe PDF formats only. Each individual or institution is requested to submit only one response. OSTP or NSTC may post responses to this RFI, without change, on a Federal website. OSTP, therefore, requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

**FOR FURTHER INFORMATION CONTACT:** Said Jahanmir, 301-975-8324, [Said.Jahanmir@nist.gov](mailto:Said.Jahanmir@nist.gov).

**SUPPLEMENTARY INFORMATION:** Public Law 113-235, The Consolidated and Further Continuing Appropriations Act 2015, incorporating the Revitalize American Manufacturing and Innovation Act of 2014 revised 42

U.S.C. 6622 to direct the National Science and Technology Council (NSTC) to develop and update, in coordination with the National Economic Council, a strategic plan to improve government coordination and provide long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including advanced manufacturing research and development (R&D). Pursuant to this requirement, NSTC seeks to develop a National Strategic Plan for Advanced Manufacturing ("Plan") that will create jobs, grow the economy across multiple industrial sectors, strengthen national security, and improve healthcare.

Advanced manufacturing refers to a family of activities relating to the use and coordination of information, automation, computation, software, sensing, networking, and interoperability to manufacture existing products in new ways, or to manufacture new products emerging from the use of new technologies.

NSTC has commenced the development of the Plan and, pursuant to 42 U.S.C. 6622, is soliciting public input through this RFI to obtain recommendations from a wide range of stakeholders, including representatives from diverse manufacturing companies, academia, and other relevant organizations and institutions. The public input provided in response to this RFI will inform OSTP and NSTC as they work with Federal agencies and other stakeholders to develop the Plan.

### Questions To Inform Development of the Plan

Through this RFI, OSTP seeks responses to the following questions to improve government coordination and provide long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including advanced manufacturing R&D. Responses should clearly indicate which question(s) is being addressed.

1. In priority order, what should be the near-term and long-term objectives for advanced manufacturing, including R&D objectives, the anticipated time frame for achieving the objectives, and the metrics for use in assessing progress toward the objectives?

2. How can Federal agencies and federally funded R&D centers supporting advanced manufacturing R&D foster the transfer of R&D results into new manufacturing technologies and United States-based manufacturing of new products and processes for the benefit of society to ensure national, energy, and economic security? What

role can public-private partnerships play, and how should they be structured for maximum impact?

3. What innovative tools, platforms, technologies are needed for advances in manufacturing? Of those that already exist, what are the barriers to their adoption?

4. How can such Federal agencies and centers develop and strengthen all levels of manufacturing education and training programs to ensure an adequate, well-trained U.S. workforce for the new advanced manufacturing jobs of the future?

5. How can such Federal agencies and centers assist small and medium-sized manufacturers in developing and implementing new products and processes?

6. How would you assess the state of the following factors and how they impact innovation and competitiveness for United States advanced manufacturing?

(a) technology transfer and commercialization activities;

(b) the adequacy of the national security industrial base;

(c) the capabilities of the domestic manufacturing workforce;

(d) export opportunities and trade policies;

(e) financing, investment, and taxation policies and practices;

(f) federal regulations;

(g) emerging technologies and markets;

(h) advanced manufacturing research and development undertaken by competing nations; and

(i) the capabilities of the manufacturing workforce of competing nations.

7. Is there any additional information related to advanced manufacturing in the United States, not requested above, that you believe OSTP should consider?

Dated: January 30, 2018.

**Ted Wackler,**

*Deputy Chief of Staff and Assistant Director.*

[FR Doc. 2018-02160 Filed 2-2-18; 8:45 am]

**BILLING CODE 3270-F8-P**

### SECURITIES AND EXCHANGE COMMISSION

[Investment Advisers Act Release No. 4850; File No. 803-00243]

### Janney Montgomery Scott LLC; Notice of Application

January 30, 2018.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice of application for an exemptive order under section 206A of

the Investment Advisers Act of 1940 ("Advisers Act") providing an exemption from the written disclosure and consent requirements of section 206(3).

**APPLICANT:** Janney Montgomery Scott LLC ("Applicant").

**RELEVANT ADVISERS ACT SECTIONS:**

Exemption requested under section 206A from the written disclosure and consent requirements of section 206(3).

**SUMMARY OF APPLICATION:**

The Applicant requests that the Commission issue an order under section 206A exempting it and Future Advisers (as defined below) from the written disclosure and consent requirements of section 206(3) with respect to principal transactions with nondiscretionary advisory client accounts.

**FILING DATES:** The application was filed on November 22, 2017.

**HEARING OR NOTIFICATION OF HEARING:**

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving the Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 26, 2018, and should be accompanied by proof of service on the Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. Applicant, c/o Laura E. Flores and Monica L. Parry, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Ave. NW, Washington, DC 20004.

**FOR FURTHER INFORMATION CONTACT:**

Laura L. Solomon, Senior Counsel, at (202) 551-6915, or Robert Shapiro, Branch Chief, at (202) 551-6821 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:**

The following is a summary of the application. The complete application may be obtained via the Commission's website at <http://www.sec.gov/rules/ia/releases.shtml> or by calling (202) 551-8090.

The Applicant seeks relief from the written disclosure and consent

requirements of section 206(3) of the Advisers Act that would be similar to relief provided by Advisers Act rule 206(3)-3T (the "Rule"), which expired by its terms on December 31, 2016. The relief sought by the Applicant, if granted, would be subject to conditions similar to those under the Rule, as well as certain revised or additional conditions.

### Applicant's Representations

1. The Applicant is registered as an investment adviser with the Commission and is a registered broker-dealer. The Applicant offers the Partners Advisory Program (the "Program"), a nondiscretionary advisory program.

2. The Applicant established the Program in 1999. Prior to December 31, 2016, the Applicant relied on the Rule to engage in principal transactions with its clients in the Program.

3. As of December 31, 2016, the Applicant had a total of 23,428 client accounts enrolled in the Program with aggregate assets of \$7,318,704,000. On the same date, 1,491 client accounts had consented to principal transactions in their Program accounts in reliance on the Rule. In 2016, 4,527 trades were effected in reliance on the Rule in the Program. Approximately 90 percent of the trades done in reliance on the Rule in this period were purchases by client accounts; the average purchase was approximately \$29,228. Approximately 10 percent of the trades done in reliance on the Rule in this period were sales from client accounts; the average sale was approximately \$30,011.

4. The Applicant acknowledges that the Order, if granted, would not be construed as relieving in any way the Applicant from acting in the best interests of an advisory client, including fulfilling the duty to seek the best execution for the particular transaction for the advisory client; nor shall it relieve the Applicant from any obligation that may be imposed by sections 206(1) or (2) of the Advisers Act or by other applicable provisions of the federal securities laws or applicable Financial Industry Regulatory Authority ("FINRA") rules.

### Applicant's Legal Analysis

1. Section 206(3) provides that it is unlawful for any investment adviser, directly or indirectly, acting as principal for its own account, knowingly to sell any security to or purchase any security from a client, without disclosing to the client in writing before the completion of the transaction the capacity in which the adviser is acting and obtaining the client's consent to the transaction. The Rule deemed an investment adviser to

be in compliance with the provisions of section 206(3) of the Advisers Act when the investment adviser, or a person controlling, controlled by, or under common control with the investment adviser, acting as principal for its own account, sold to or purchased from an advisory client any security, provided that the investment adviser complied with the conditions of the Rule.

2. The Rule required, among other things, that the investment adviser obtain a client's written, revocable consent prospectively authorizing the adviser, directly or indirectly, acting as principal for its own account, to sell any security to or purchase any security from the client. The consent was required to be obtained after the adviser provided the client with written disclosure about: (i) The circumstances under which the investment adviser may engage in principal transactions with the client; (ii) the nature and significance of the conflicts the investment adviser has with its client's interests as a result of those transactions; and (iii) how the investment adviser addresses those conflicts. The investment adviser also was required to provide trade-by-trade disclosure to the client, before the execution of each principal transaction, of the capacity in which the adviser may act with respect to the transaction, and obtain the client's consent (which may be written or oral) to the transaction. The Rule was available only to an investment adviser that was also a broker-dealer registered under section 15 of the Securities Exchange Act of 1934 ("Exchange Act") and could only be relied upon with respect to a nondiscretionary account that was a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member. The Rule was not available for principal transactions if the investment adviser or a person who controlled, was controlled by, or was under common control with the adviser ("control person") was the issuer or an underwriter of the security (except that an investment adviser could rely on the Rule for trades in which the investment adviser or a control person was an underwriter of non-convertible investment-grade debt securities).

3. The Rule also required the investment adviser to provide to the client a trade confirmation that, in addition to the requirements of rule 10b-10 under the Exchange Act, included a conspicuous, plain English statement informing the client that the investment adviser disclosed to the client before the execution of the transaction that the investment adviser

may act as principal in connection with the transaction, that the client authorized the transaction, and that the investment adviser sold the security to or bought the security from the client for its own account. The investment adviser also was required to deliver to the client, at least annually, a written statement listing all transactions that were executed in the account in reliance on the Rule, including the date and price of each transaction.

4. The Rule expired on December 31, 2016. Absent the requested relief, the Applicant would be required to provide trade-by-trade written disclosure to each nondiscretionary advisory client with whom the Applicant sought to engage in a principal transaction in accordance with section 206(3). The Applicant submits that its nondiscretionary clients have had access to the Applicant's inventory through principal transactions with the Applicant for a number of years, and expect to continue to have such access in the future. The Applicant believes that engaging in principal transactions with its clients provides certain benefits to its clients, including access to securities of limited availability, such as municipal bonds, and that the written disclosure and client consent requirements of section 206(3) act as an operational barrier to its ability to engage in principal trades with its clients, especially when the transaction involves securities of limited availability.

5. Unless the Applicant is provided an exemption from the written disclosure and client consent requirements of section 206(3), the Applicant believes that it will be unable to provide the same range of services and access to the same types of securities to its nondiscretionary advisory clients as it was able to provide to its clients under the Rule.

6. The Applicant notes that, if the requested relief is granted, it will remain subject to the fiduciary duties that are generally enforceable under sections 206(1) and 206(2) of the Advisers Act, which, in general terms, require the Applicant to: (i) Disclose material facts about the advisory relationship to its clients; (ii) treat each client fairly; and (iii) act only in the best interests of its client, disclosing conflicts of interest when present and obtaining client consent to arrangements that present such conflicts.

7. The Applicant further notes that, in its capacity as a broker-dealer with respect to these accounts, it will remain subject to a comprehensive set of Commission and FINRA regulations that apply to the relationship between a broker-dealer and its customer in

addition to the fiduciary duties an adviser owes a client. These rules require, among other things, that the Applicant deal fairly with its customers, seek to obtain best execution of customer orders, and make only suitable recommendations. These obligations are designed to promote business conduct that protects customers from abusive practices that may not necessarily be fraudulent, and to protect against unfair prices and excessive commissions. Specifically, these provisions, among other things, require that the prices charged by the Applicant be reasonably related to the prevailing market, and limit the commissions and mark-ups the Applicant can charge. Additionally, these obligations require that the Applicant have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on information obtained through reasonable diligence.

8. The Applicant requests that the Commission issue an Order pursuant to section 206A exempting it from the written disclosure and consent requirements of section 206(3) only with respect to client accounts in the Program and any similar nondiscretionary program to be created in the future. The Applicant also requests that the Commission's Order apply to future investment advisers controlling, controlled by, or under common control with the Applicant ("Future Advisers"). Any Future Adviser relying on any Order granted pursuant to the application will comply with the terms and conditions stated in the application.<sup>1</sup>

#### Applicant's Conditions

The Applicant agrees that any Order granting the requested relief will be subject to the following conditions:

1. The Applicant will exercise no "investment discretion" (as such term is defined in section 3(a)(35) of the Exchange Act), except investment discretion granted by the advisory client on a temporary or limited basis,<sup>2</sup> with respect to the client's account.

<sup>1</sup> All entities that currently intend to rely on any order granted pursuant to the application are named as Applicants.

<sup>2</sup> Discretion is considered to be temporary or limited for purposes of this condition when the investment adviser is given discretion: (i) As to the price at which or the time to execute an order given by a client for the purchase or sale of a definite amount or quantity of a specified security; (ii) on an isolated or infrequent basis, to purchase or sell a security or type of security when a client is unavailable for a limited period of time not to exceed a few months; (iii) as to cash management, such as to exchange a position in a money market fund for another money market fund or cash equivalent; (iv) to purchase or sell securities to

2. The Applicant will not trade in reliance on this Order any security for which the Applicant or any person controlling, controlled by, or under common control with the Applicant is the issuer, or, at the time of the sale, an underwriter (as defined in section 202(a)(20) of the Advisers Act).

3. The Applicant will not directly or indirectly require the client to consent to principal trading as a condition to opening or maintaining an account with the Applicant.

4. The advisory client has executed a written revocable consent prospectively authorizing the Applicant directly or indirectly to act as principal for its own account in selling any security to or purchasing any security from the advisory client. The advisory client's written consent must be obtained through a signature or other positive manifestation of consent that is separate from or in addition to the signature indicating the client's consent to the advisory agreement. The separate or additional signature line or alternative means of expressing consent must be preceded immediately by prominent, plain English disclosure containing either: (a) An explanation of: (i) The circumstances under which the Applicant directly or indirectly may engage in principal transactions; (ii) the nature and significance of conflicts with its client's interests as a result of the transactions; and (iii) how the Applicant addresses those conflicts; or (b) a statement explaining that the client is consenting to principal transactions, followed by a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)-(iii) above and to the specific page or pages on which such disclosure is located; provided, however, that if the Applicant requires time to modify its electronic systems to provide the specific page cross-reference required by clause (b), the Applicant may, while updating such electronic systems, and for no more than 90 days from the date of the Order, instead provide a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)-(iii) above and to the specific section in such document in which such disclosure is located.

*Transition provision:* To the extent that the Applicant obtained fully

satisfy margin requirements; (v) to sell specific bonds and purchase similar bonds in order to permit a client to take a tax loss on the original position; (vi) to purchase a bond with a specified credit rating and maturity; and (vii) to purchase or sell a security or type of security limited by specific parameters established by the client. *See, e.g., Temporary Rule Regarding Principal Trades with Certain Advisory Clients*, Investment Advisers Act Release No. 2653 (Sept. 24, 2007) at n. 31.

informed written revocable consent from an advisory client for purposes of rule 206(3)-3T(a)(3) prior to January 1, 2017, the Applicant may rely on this Order with respect to such client without obtaining additional prospective consent from such client.

5. The Applicant, prior to the execution of each transaction in reliance on this Order, will: (a) Inform the advisory client, orally or in writing, of the capacity in which it may act with respect to such transaction; and (b) obtain consent from the advisory client, orally or in writing, to act as principal for its own account with respect to such transaction.

6. The Applicant will send a written confirmation at or before completion of each such transaction that includes, in addition to the information required by rule 10b-10 under the Exchange Act, a conspicuous, plain English statement informing the advisory client that the Applicant: (a) Disclosed to the client prior to the execution of the transaction that the Applicant may be acting in a principal capacity in connection with the transaction and the client authorized the transaction; and (b) sold the security to, or bought the security from, the client for its own account.

7. The Applicant will send to the client, no less frequently than annually, written disclosure containing a list of all transactions that were executed in the client's account in reliance upon this Order, and the date and price of each such transaction.

8. The Applicant is a broker-dealer registered under section 15 of the Exchange Act and each account for which the Applicant relies on this Order is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member.

9. Each written disclosure required as a condition to this Order will include a conspicuous, plain English statement that the client may revoke the written consent referred to in Condition 4 above without penalty at any time by written notice to the Applicant in accordance with reasonable procedures established by the Applicant, but in all cases such revocation must be given effect within 5 business days of the Applicant's receipt thereof.

10. The Applicant will maintain records sufficient to enable verification of compliance with the conditions of this Order. Such records will include, *without limitation*: (a) Documentation sufficient to demonstrate compliance with each disclosure and consent requirement under this Order; (b) in particular, documentation sufficient to demonstrate that, prior to the execution

of each transaction in reliance on this Order, the Applicant informed the relevant advisory client of the capacity in which the Applicant may act with respect to the transaction and that it received the advisory client's consent (if the Applicant informs the client orally of the capacity in which it may act with respect to such transaction or obtains oral consent, such records may, for example, include recordings of telephone conversations or contemporaneous written notations); and (c) documentation sufficient to enable assessment of compliance by the Applicant with sections 206(1) and (2) of the Advisers Act in connection with its reliance on this Order.<sup>3</sup> In each case, such records will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

11. The Applicant will adopt written compliance policies and procedures reasonably designed to ensure, and the Applicant's chief compliance officer will monitor, the Applicant's compliance with the conditions of this Order. The Applicant's chief compliance officer will, on at least a quarterly basis, conduct testing reasonably sufficient to verify such compliance. Such written policies and procedures, monitoring and testing will address, *without limitation*: (a) Compliance by the Applicant with its disclosure and consent requirements under this Order; (b) the integrity and operation of electronic systems employed by the Applicant in connection with its reliance on this Order; (c) compliance by the Applicant with its recordkeeping obligations under this Order; and (d) whether there is any evidence of the Applicant engaging in "dumping" in connection with its reliance on this Order.<sup>4</sup> The Applicant's chief compliance officer will document the frequency and results of such monitoring and testing, and the Applicant will maintain and preserve

<sup>3</sup> For example, under sections 206(1) and (2), an investment adviser may not engage in any transaction on a principal basis with a client that is not consistent with the best interests of the client or that subrogates the client's interests to the interests of the investment adviser. Cf. Investment Advisers Act Release No. 2106 (Jan. 31, 2003) (adopting Rule 206(4)-6).

<sup>4</sup> See Report of the Securities and Exchange Commission, Investment Trusts and Investment Companies, H.R. Doc. No. 279, 76th Cong., 2d Sess., pt. 3, at 2581, 2589 (1939); Hearings on S. 3580 Before a Subcommittee of the Commission on Banking and Currency, 76th Cong., 3d Sess. 209, 212-23 (1940); Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 322 (1940).

such documentation in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

For the Commission, by the Division of Investment Management, under delegated authority.

**Eduardo A. Aleman,**  
Assistant Secretary.

[FR Doc. 2018-02168 Filed 2-2-18; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32999; 812-14859]

### Gadsden ETF Trust and Gadsden, LLC

January 30, 2018.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c-1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) actively-managed series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds; and (f) certain Funds ("Feeder Funds") to create and redeem Creation Units in-kind in a master-feeder structure.

**APPLICANTS:** Gadsden ETF Trust ("Trust"), a Delaware statutory trust that will be registered under the Act as an

open-end management investment company with multiple series, and Gadsden, LLC ("Initial Adviser"), a Delaware limited liability company that will be registered as an investment adviser under the Investment Advisers Act of 1940.

**FILING DATES:** The application was filed on December 26, 2017.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 23, 2018, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090; Applicants: Eight Tower Bridge, 161 Washington Street, Suite 580, Conshohocken, PA 19428.

**FOR FURTHER INFORMATION CONTACT:** Bruce R. MacNeil, Senior Counsel, at (202) 551-6817, or David J. Marcinkus, Branch Chief, at (202) 551-6821 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

### Summary of the Application

1. Applicants request an order that would allow Funds to operate as actively-managed exchange traded funds ("ETFs").<sup>1</sup> Fund shares will be

<sup>1</sup> Applicants request that the order apply to the Initial Fund, as well as to future series of the Trust, and any other open-end management investment companies or series thereof (each, included in the term "Fund"), each of which will operate as an actively-managed ETF. Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each, an

purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an “Authorized Participant,” which will have signed a participant agreement with a broker-dealer registered under the Securities Exchange Act of 1934 (“Exchange Act”) (the “Distributor”). Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a master-feeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will consist of a portfolio of securities and other assets and investment positions (“Portfolio Instruments”). Each Fund will disclose on its website the identities and quantities of the Portfolio Instruments that will form the basis for the Fund’s calculation of NAV at the end of the day.

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (“Deposit Instruments”), and shareholders redeeming their shares will receive specified instruments (“Redemption Instruments”). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund’s portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c-1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund’s prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment

in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that hold non-U.S. Portfolio Instruments and that effect creations and redemptions of Creation Units in kind, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application’s terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit a person who is an affiliated person, as defined in section 2(a)(3) of the Act (“Affiliated Person”), or an affiliated person of an Affiliated Person (“Second-Tier Affiliate”), of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those Portfolio Instruments currently held by

the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.<sup>2</sup> The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund (“Master Fund”) beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

<sup>2</sup> The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an investment adviser to a Fund of Funds is also an investment adviser to a Fund of Funds.

“Adviser”) and (b) comply with the terms and conditions of the application.

For the Commission, by the Division of Investment Management, under delegated authority.

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018-02170 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32998; File No. 812-14842]

### Columbia Funds Series Trust, et al.

January 30, 2018.

**AGENCY:** Securities and Exchange Commission (“Commission”).

**ACTION:** Notice.

Notice of an application for an order pursuant to: (a) Section 6(c) of the Investment Company Act of 1940 (“Act”) granting an exemption from sections 18(f) and 21(b) of the Act; (b) section 12(d)(1)(J) of the Act granting an exemption from section 12(d)(1) of the Act; (c) sections 6(c) and 17(b) of the Act granting an exemption from sections 17(a)(1), 17(a)(2) and 17(a)(3) of the Act; and (d) section 17(d) of the Act and rule 17d-1 under the Act to permit certain joint arrangements and transactions. Applicants request an order that would permit certain registered open-end management investment companies to participate in a joint lending and borrowing facility.<sup>1</sup>

**APPLICANTS:** Columbia Funds Series Trust, Columbia Funds Series Trust I, Columbia Funds Series Trust II, Columbia Funds Variable Insurance Trust, Columbia Funds Variable Series Trust II, Columbia ETF Trust I and Columbia ETF Trust II (each a “Trust” and collectively, the “Trusts”), each registered under the Act as open-end management investment companies with one or more series, and Columbia Management Investment Advisers, LLC (“Columbia Management”), registered as an investment adviser under the Investment Advisers Act of 1940.

**FILING DATE:** The application was filed on November 9, 2017.

<sup>1</sup> The requested order would supersede an exemptive order issued by the Commission on October 24, 2006, with the result that no person will continue to rely on the prior order if the order is granted. *RiverSource Diversified Income Series, Inc., et al.*, Investment Company Act Release Nos. 27506 (September 28, 2006) (notice) and 27525 (October 24, 2016) (order). All existing entities that currently intend to rely on the order have been named as applicants. Any other existing or future entity that relies on the order in the future will comply with the terms and conditions of the application.

### HEARING OR NOTIFICATION OF HEARING:

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 26, 2018 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0-5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090; Applicants: c/o Brian D. McCabe, Esq. and Nathan D. Somogie, Esq., Rope & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA 02199.

**FOR FURTHER INFORMATION CONTACT:** Hae-Sung Lee, Attorney-Adviser, at (202) 551-7345 or Robert H. Shapiro, Branch Chief, at (202) 551-6821 (Division of Investment Management, Chief Counsel’s Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission’s website by searching for the file number, or an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

### Summary of the Application

1. Applicants request an order that would permit the applicants to participate in an interfund lending facility where each Fund could lend money directly to and borrow money directly from other Funds to cover unanticipated cash shortfalls, such as unanticipated redemptions or trade fails.<sup>2</sup> The Funds will not borrow under

<sup>2</sup> Applicants request that the order apply to the applicants and to any existing or future series of the Trusts and to any other registered open-end or closed-end management investment company or its series for which Columbia Management and each successor thereto or a person controlling, controlled by, or under common control with Columbia Management serves as investment adviser (each such investment adviser may be referred to as an “Adviser” and collectively, the “Advisers”). For purposes of the requested order, “successor” is limited to any entity that results from a reorganization into another jurisdiction or a change in the type of a business organization. The Funds that are closed-end management investment

the facility for leverage purposes and the loans’ duration will be no more than 7 days.<sup>3</sup>

2. Applicants anticipate that the proposed facility would provide a borrowing Fund with a source of liquidity at a rate lower than the bank borrowing rate at times when the cash position of the Fund is insufficient to meet temporary cash requirements. In addition, Funds making short-term cash loans directly to other Funds would earn interest at a rate higher than they otherwise could obtain from investing their cash in repurchase agreements or certain other short term money market instruments. Thus, applicants assert that the facility would benefit both borrowing and lending Funds.

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the Application. Among others, the Adviser, through a designated committee, would administer the facility as a disinterested fiduciary as part of its duties under the investment management and administrative agreements with the Funds and would receive no additional fee as compensation for its services in connection with the administration of the facility. The facility would be subject to oversight and certain approvals by the Funds’ Board, including, among others, approval of the interest rate formula and of the method for allocating loans across Funds, as well as review of the process in place to evaluate the liquidity implications for the Funds. A Fund’s aggregate outstanding interfund loans will not exceed 15% of its net assets, and the Fund’s loans to any one Fund will not exceed 5% of the lending Fund’s net assets.<sup>4</sup>

4. Applicants assert that the facility does not raise the concerns underlying section 12(d)(1) of the Act given that the Funds are part of the same group of investment companies and there will be no duplicative costs or fees to the Funds.<sup>5</sup> Applicants also assert that the proposed transactions do not raise the concerns underlying sections 17(a)(1), 17(a)(3), 17(d) and 21(b) of the Act as the Funds would not engage in lending transactions that unfairly benefit

companies will not participate as borrowers in the interfund lending facility.

<sup>3</sup> Any Fund, however, will be able to call a loan on one business day’s notice.

<sup>4</sup> Under certain circumstances, a borrowing Fund will be required to pledge collateral to secure the loan.

<sup>5</sup> Applicants state that the obligation to repay an interfund loan could be deemed to constitute a security for the purposes of sections 17(a)(1) and 12(d)(1) of the Act.

insiders or are detrimental to the Funds. Applicants state that the facility will offer both reduced borrowing costs and enhanced returns on loaned funds to all participating Funds and each Fund would have an equal opportunity to borrow and lend on equal terms based on an interest rate formula that is objective and verifiable. With respect to the relief from section 17(a)(2) of the Act, applicants note that any collateral pledged to secure an interfund loan would be subject to the same conditions imposed by any other lender to a Fund that imposes conditions on the quality of or access to collateral for a borrowing (if the lender is another Fund) or the same or better conditions (in any other circumstance).<sup>6</sup>

5. Applicants also believe that the limited relief from section 18(f)(1) of the Act that is necessary to implement the facility (because the lending Funds are not banks) is appropriate in light of the conditions and safeguards described in the application and because the Funds would remain subject to the requirement of section 18(f)(1) that all borrowings of a Fund, including combined interfund loans and bank borrowings, have at least 300% asset coverage.

6. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Rule 17d-1(b) under the Act provides that in passing upon an application filed under the rule, the Commission will

<sup>6</sup> Applicants state that any pledge of securities to secure an interfund loan could constitute a purchase of securities for purposes of section 17(a)(2) of the Act.

consider whether the participation of the registered investment company in a joint enterprise, joint arrangement or profit sharing plan on the basis proposed is consistent with the provisions, policies and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of the other participants.

For the Commission, by the Division of Investment Management, under delegated authority.

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2018-02169 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82604; File No. SR-NASDAQ-2018-007]

### Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate the Consolidated Audit Trail Compliance Rules

January 30, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on January 29, 2018, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to relocate the Consolidated Audit Trail Compliance rules (“CAT Rules”), currently under the 6800 Series (Rules 6810 through 6896), to General 7, Sections 1 through 13 in the Exchange’s rulebook’s (“Rulebook”) shell structure.<sup>3</sup>

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, Nasdaq BX, Inc.; Nasdaq PHLX LLC; Nasdaq ISE, LLC; Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (“Affiliated Exchanges”). See Securities Exchange Act Release No. 82175 (November 29, 2017), 82 FR 57494 (December 5, 2017) (SR-NASDAQ-2017-125).

The text of the proposed rule change is available on the Exchange’s website at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

#### II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes to relocate the CAT Rules, currently under the 6800 Series, Rules 6810 through 6896, to General 7, Sections 1 through 13 of the Rulebook’s shell structure.

The Exchange adopted the CAT Rules to implement a consolidated audit trail in order to capture customer and order event information to comply with the provisions of the National Market System Plan Governing the Consolidated Audit Trail.<sup>4</sup> Because the CAT Rules apply across all markets and to all products,<sup>5</sup> the Exchange believes it is pertinent that they be located in the General section of the Rulebook’s shell; therefore, the Exchange will amend the shell structure, creating a new “General 7 Consolidated Audit Trail Compliance” title under “General Equity and Options Rules,” and make conforming changes to the “Options Rules” titles; moreover, this proposal is consistent with similar filings concurrently submitted by the Affiliated Exchanges.

The relocation of the CAT Rules is part of the Exchange’s continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.<sup>6</sup> The Exchange believes that the migration of the CAT Rules to their new location will facilitate the use of

<sup>4</sup> See Securities Exchange Act Release No. 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017) (SR-NASDAQ-2017-008) (Order Approving Proposed Rule Changes To Adopt Consolidated Audit Trail Compliance Rules).

<sup>5</sup> *Id.*

<sup>6</sup> See footnote 3.

the Rulebook by Members<sup>7</sup> of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a non-substantive nature and will not amend the relocated rules other than to update their numbers and make conforming cross-reference changes.

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>8</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>9</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and conformity of the Exchange's processes with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the relocation of the CAT Rules and cross-reference updates are of a non-substantive nature.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they (i) are of a non-substantive nature, (ii) are intended to harmonize the Exchange's rules with those of its Affiliated Exchanges, and (iii) are intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time

as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>10</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>11</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>12</sup> normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)<sup>13</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange can reorganize its Rulebook as already approved by the Commission. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change as operative upon filing.<sup>14</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

### Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

<sup>10</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>11</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>12</sup> 17 CFR 240.19b-4(f)(6).

<sup>13</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>14</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NASDAQ-2018-007 on the subject line.

### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2018-007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2018-007 and should be submitted on or before February 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>15</sup>

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018-02171 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

*Upon Written Request, Copies Available From: Securities and Exchange*

<sup>15</sup> 17 CFR 200.30-3(a)(12).

<sup>7</sup> Exchange Rule 0120(i).

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(5).

Commission, Office of FOIA Services,  
100 F Street NE, Washington, DC  
20549-2736

*Extension:*

Rule 35d-1, SEC File No. 270-491, OMB  
Control No. 3235-0548

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 35d-1 (17 CFR 270.35d-1) under the Investment Company Act of 1940 (15 U.S.C. 80a-1 *et seq.*) defines as "materially deceptive and misleading" for purposes of Section 35(d), among other things, a name suggesting that a registered investment company or series thereof (a "fund") focuses its investments in a particular type of investment or investments, in investments in a particular industry or group of industries, or in investments in a particular country or geographic region, unless, among other things, the fund adopts a certain investment policy. Rule 35d-1 further requires either that the investment policy is fundamental or that the fund has adopted a policy to provide its shareholders with at least 60 days prior notice of any change in the investment policy ("notice to shareholders"). The rule's notice to shareholders provision is intended to ensure that when shareholders purchase shares in a fund based, at least in part, on its name, and with the expectation that it will follow the investment policy suggested by that name, they will have sufficient time to decide whether to redeem their shares in the event that the fund decides to pursue a different investment policy.

The Commission estimates that there are approximately 9,939 open-end and closed-end funds that have names that are covered by the rule. The Commission estimates that of these 9,939 funds, approximately 33 will provide prior notice to shareholders pursuant to a policy adopted in accordance with this rule per year. The Commission estimates that the annual burden associated with the notice to shareholders requirement of the rule is 20 hours per response, for annual total of 660 hours per year.

Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the

costs of Commission rules and forms. The collection of information under rule 35d-1 is mandatory. The information provided under rule 35d-1 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE, Washington, DC 20549; or send an email to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: January 31, 2018.

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2018-02257 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

*Extension:*

Rule 17g-3, SEC File No. 270-563, OMB  
Control No. 3235-0626

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 17g-3 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).<sup>1</sup> The Commission plans to submit this existing collection

<sup>1</sup> See 17 CFR 240.17g-1 and 17 CFR 249b.300.

of information to the Office of Management and Budget for extension and approval.

Rule 17g-3 contains certain reporting requirements for NRSROs including financial statements and information concerning its financial condition that the Commission, by rule, may prescribe as necessary or appropriate in the public interest or for the protection of investors. Currently, there are 10 credit rating agencies registered as NRSROs with the Commission. The Commission estimates that the total burden for respondents to comply with Rule 17g-3 is 3,650 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F St NE, Washington, DC 20549 or send an email to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: January 31, 2018.

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2018-02255 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services,

100 F Street NE, Washington, DC  
20549-2736

*Extension:*

Rule 17g-10 and Form ABS Due Diligence-15 E SEC File No. 270-563, OMB Control No. 3235-0694

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the existing collection of information provided for in Rule 17g-10 and Form ABS Due Diligence-15 E under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).<sup>1</sup> The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 17g-10 contains certain certification requirements for third-party due diligence service providers that are employed by an NRSRO, an issuer, or an underwriter, which must be made on Form ABS Due Diligence-15E. The Commission estimates that the total burden for respondents to comply with Rule 17g-10 is 238 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F St NE, Washington, DC 20549 or send an email to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: January 31, 2018.

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018-02256 Filed 2-2-18; 8:45 am]

**BILLING CODE 8011-01-P**

**DEPARTMENT OF STATE**

**[Public Notice: 10281]**

**60-Day Notice of Proposed Information Collection: Advance Notification Form; Tourist and Other Non-Governmental Activities in the Antarctic Treaty Area**

**ACTION:** Notice of request for public comment.

**SUMMARY:** The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

**DATES:** The Department will accept comments from the public up to April 6, 2018.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to [www.Regulations.gov](http://www.Regulations.gov). You can search for the document by entering “Docket Number: DOS-2018-0006” in the Search field. Then click the “Comment Now” button and complete the comment form.

- *Email:* [GanserPJ@State.gov](mailto:GanserPJ@State.gov).

- *Regular Mail:* Send written comments to: Peter Ganser, Office of Ocean and Polar Affairs, Room 2665, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State, 2201 C Street NW, Washington, DC 20520.

You must include the DS form number, DS-4131; information collection title, ADVANCE NOTIFICATION FORM: Tourist and Other Non-Governmental Activities in the Antarctic Treaty Area; and the OMB control number, 1405-0181, in any correspondence.

**FOR FURTHER INFORMATION CONTACT:**

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, may be submitted to Peter Ganser, Office of Ocean and Polar Affairs, Room

2665, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State, 2201 C Street NW, Washington, DC 20520. He may be reached on 202-647-0237.

**SUPPLEMENTARY INFORMATION:**

- *Title of Information Collection:* ADVANCE NOTIFICATION FORM: Tourist and Other Non-Governmental Activities in the Antarctic Treaty Area.

- *OMB Control Number:* 1405-0181.

- *Type of Request:* Extension of a Currently Approved Collection.

- *Originating Office:* Bureau of Oceans and International Environmental and Scientific Affairs (OES/OPA).

- *Form Number:* DS-4131.

- *Respondents:* Operators of Antarctic expeditions organized in or proceeding from the United States.

- *Estimated Number of Respondents:* 25.

- *Estimated Number of Responses:* 25.

- *Average Time per Response:* 10.5 hours.

- *Total Estimated Burden Time:* 260 hours.

- *Frequency:* On occasion.

- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

**Abstract of Proposed Collection**

Information solicited on the Advance Notification Form (DS-4131) provides the U.S. Government with information on tourist and other non-governmental expeditions to the Antarctic Treaty area. The U.S. Government needs this information to comply with Article VII(5)(a) of the Antarctic Treaty and associated documents.

<sup>1</sup> See 17 CFR 240.17g-1 and 17 CFR 249b.300.

**Methodology**

Information will be submitted by organizers of tourist and other non-governmental expeditions to Antarctica. Copies should be submitted via email, although signed originals are also valid.

**Evan T. Bloom,**

*Director, Office of Ocean and Polar Affairs, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State.*

[FR Doc. 2018-02191 Filed 2-2-18; 8:45 am]

**BILLING CODE 4710-09-P**

**DEPARTMENT OF STATE**

[Public Notice: 10297]

**Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: “Peacock in the Desert: The Royal Arts of Jodhpur, India” Exhibition**

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Peacock in the Desert: The Royal Arts of Jodhpur, India,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Museum of Fine Arts, Houston, in Houston, Texas, from on or about March 4, 2018, until on or about August 12, 2018, at the Seattle Art Museum, Seattle, Washington, from on or about October 11, 2018, until on or about January 13, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest.

**FOR FURTHER INFORMATION CONTACT:**

Elliot Chiu in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257-1 of December 11,

2015). I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**Alyson Grunder,**

*Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-02188 Filed 2-2-18; 8:45 am]

**BILLING CODE 4710-05-P**

**DEPARTMENT OF STATE**

[Public Notice: 10293]

**U.S. Department of State Advisory Committee on Private International Law (ACPIL): Public Meeting on Online Dispute Resolution**

The Office of the Assistant Legal Adviser for Private International Law, Department of State, hereby gives notice that the APCIL will hold a public meeting via teleconference to discuss a pending proposal on online dispute resolution (ODR) in the Asia Pacific Economic Cooperation forum (APEC). This is not a meeting of the full Advisory Committee.

In February 2017, the APEC Economic Committee endorsed a work plan on development of an APEC-wide cooperative framework for ODR for Micro, Small, and Medium Sized Enterprises (MSMEs) in business-to-business (B2B) transactions, which is currently co-sponsored by thirteen member economies (namely, Australia, Chile, Canada, Hong Kong, China, Indonesia, Japan, Mexico, New Zealand, Papua New Guinea, Peru, Russia, Chinese Taipei and the United States).

MSMEs have gained unprecedented access to international trade via the global supply chain and cross-border e-commerce, but to effectively reach global markets these businesses need a legal environment which enables the quick resolution of disputes and creates confidence in cross-border e-commerce. The use of ODR could be an effective means to solve this problem. ODR is a way of resolving disputes using traditional methods such as negotiation, mediation, and arbitration, but with the help of technology and without the need for a physical presence at a meeting or hearing.

At its most recent meeting in August 2017, the APEC Economic Committee endorsed a revised work plan on ODR that includes calls to inter alia “build a pilot in conjunction with platform host/ODR provider via outreach to regional arbitration/mediation centers to determine possible partners for hosting ODR platform.” Additionally, the scope of the project was expanded to include

“Use of Modern Technology for Dispute Resolution and Electronic Agreement Management” with the explanation that “it is also worthwhile to explore the use of other modern technology such as block chain, automated or smart contracts for contract management or enforcement and prevention of disputes.” The APEC Economic Committee has approved a two-day workshop for the first Economic Committee meeting next February to discuss the work plan and the pilot proposal.

This conference call will be a continuation of the conference call meeting that was held on November 1, 2017.

*Time and Place:* The ACPIL meeting will take place on Thursday, February 15, 2018 from 10 a.m. to 1:00 p.m. EST via teleconference.

*Public Participation:* Those planning to participate should email [pil@state.gov](mailto:pil@state.gov) to obtain the call-in number.

**Michael J. Dennis,**

*Attorney-Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.*

[FR Doc. 2018-02174 Filed 2-2-18; 8:45 am]

**BILLING CODE 7410-08-P**

**DEPARTMENT OF STATE**

[Public Notice: 10299]

**Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: “Michelangelo and the Vatican: Masterworks From the Museo e Real Bosco di Capodimonte, Naples” Exhibition**

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Michelangelo and the Vatican: Masterworks from the Museo e Real Bosco di Capodimonte, Naples,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Museum of Fine Arts, Houston, in Houston, Texas, from on or about March 11, 2018, until on or about June 10, 2018, and at possible additional exhibitions or venues yet to be determined, is in the national interest.

**FOR FURTHER INFORMATION CONTACT:** Elliot Chiu in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email:

section2459@state.gov). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257-1 of December 11, 2015). I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**Alyson Grunder,**

*Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-02190 Filed 2-2-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[Public Notice: 10294]

### U.S. Department of State Advisory Committee on Private International Law (ACPIL): Public Meeting in Advance of Meeting of United Nations Commission on International Trade Law (UNCITRAL) Working Group I-Micro, Small, and Medium-Sized Enterprises

The Office of the Assistant Legal Adviser for Private International Law, Department of State, hereby gives notice that the Micro, Small, and Medium-Sized Enterprises (MSMEs) study group of the Advisory Committee on Private International Law (ACPIL) will hold a public meeting via teleconference to discuss the next session of the UNCITRAL Working Group I scheduled for March 12-16 in New York. This is not a meeting of the full Advisory Committee.

UNCITRAL has established a working group aimed at reducing the legal obstacles faced by MSMEs throughout their life cycle, and in particular those in developing countries. UNCITRAL further directed that the work should start with a focus on the legal issues surrounding the simplification of registration and incorporation. At its upcoming session, the UNCITRAL Working Group I will attempt to complete consideration of a draft legislative guide on key principles of business registration (UN Doc. A/CN.9/WG.I/WP.106) and an introductory

paper prepared by the Secretariat entitled "Reducing the legal obstacles faced by MSMEs" (UN Doc. A/CN.9/WG.I/WP.107). Once those tasks had been completed, the Working Group would resume its consideration of the draft legislative guide on an UNCITRAL Limited Liability Organization found in documents A/CN.9/WG.I/WP.99 and A/CN.9/WG.I/WP.99/Add.1. Draft texts, along with the reports of earlier sessions of the Working Group will be available at [http://www.uncitral.org/uncitral/en/commission/working\\_groups/1MSME.html](http://www.uncitral.org/uncitral/en/commission/working_groups/1MSME.html).

**Time and Place:** The ACPIL public meeting will take place on Tuesday, February 20, 2018, from 10 a.m. to 12:00 p.m. EDT via teleconference.

**Public Participation:** Those planning to participate should email [pil@state.gov](mailto:pil@state.gov) to obtain the call-in number.

**Michael J. Dennis,**

*Attorney-Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.*

[FR Doc. 2018-02175 Filed 2-2-18; 8:45 am]

**BILLING CODE 7410-08-P**

## DEPARTMENT OF STATE

[Public Notice: 10298]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: "Icons of Style: A Century of Fashion Photography, 1911-2011" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition "Icons of Style: A Century of Fashion Photography, 1911-2011," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum at the Getty Center, Los Angeles, California, from on or about June 26, 2018, until on or about October 21, 2018, and at possible additional exhibitions or venues yet to be determined, is in the national interest.

**FOR FURTHER INFORMATION CONTACT:**

Elliot Chiu in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**SUPPLEMENTARY INFORMATION:** The foregoing determinations were made

pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257-1 of December 11, 2015). I have ordered that Public Notice of these determinations be published in the **Federal Register**.

**Alyson Grunder,**

*Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2018-02189 Filed 2-2-18; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### Notice of OFAC Sanctions Actions

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

**DATES:** See **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

OFAC: Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Licensing, tel.: 202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202-622-2410.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (<http://www.treasury.gov/ofac>).

## Notice of OFAC Actions

On January 30, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

### Individuals

1. WEI, Zhao (a.k.a. CHIO, Wai; a.k.a. HWEL, Jao; a.k.a. SAECHOU, Thanchai; a.k.a. WAI, Chio; a.k.a. WEI, Chao; a.k.a. WEI, Jiao; a.k.a. WEI, Zhang), Flat G, 19 FL Maple Mansion, Taikoo Shing, Quarry Bay, Hong Kong; Room 2410, 24/F, Block Q, Kornhill, Quarry Bay, Hong Kong; DOB 16 Sep 1952; POB Heilongjiang Province, China; alt. POB Liaoning Province, China; nationality China; Gender Male; Passport MA0269785 (Macau); alt. Passport M0178952 (China); alt. Passport MA0162634 (China); National ID No. 12756003 (Macau) (individual) [TCO] (Linked To: ZHAO WEI TCO). Designated pursuant to section 1(a)(ii)(B) of Executive Order 13581 of July 24, 2011, "Blocking Property of Transnational Criminal Organizations" (E.O. 13581), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the ZHAO WEI TCO. Also designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the ZHAO WEI TCO.

2. SU, Guiqin (a.k.a. SU, Gui Qin; a.k.a. SU, Madame; a.k.a. SU, Zhao; a.k.a. WEI, Su), Flat G, 19 FL Maple Mansion, Taikoo Shing, Quarry Bay, Hong Kong; DOB 03 Dec 1959; POB Liaoning Province, China; nationality China; Gender Female; Passport G55408772 (China); alt. Passport G42695702 (China); alt. Passport E03807847 (China); National ID No. R9733840 (China) (individual) [TCO] (Linked To: ZHAO WEI TCO). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the ZHAO WEI TCO. Also designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the ZHAO WEI TCO.

3. EBERAHIM, Abbas (a.k.a. BASU), 43 Walana Cres, Koorringal, NSW 2650, Australia; Golden Triangle Special Economic Zone, Bokeo, Laos; 292 Moo 1 Wiang, Chiang Saen District, Chiang Rai 57150, Thailand; DOB 11 Sep 1949; POB Malaysia; nationality Australia; Gender Male; Passport N2315963 (Australia) (individual) [TCO] (Linked To: ZHAO WEI TCO). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the ZHAO WEI TCO. Also designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the ZHAO WEI TCO.

4. RUNGTAWANKHIRI, Nat (a.k.a. RUNGTAWANKEEREE, Nat), 100 (20) Mu. 2, Tambon Mae Salong Nai, Mae Fah Luang

District, Chiang Rai, Thailand; DOB 01 Jan 1977; nationality Thailand; Gender Male; National ID No. 5-5715-00025-50-6 (Thailand) (individual) [TCO] (Linked To: ZHAO WEI TCO). Designated pursuant to section 1(a)(ii)(B) of E.O. 13581 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the ZHAO WEI TCO. Also designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the ZHAO WEI TCO.

### Entities

1. ZHAO WEI TCO (a.k.a. KINGS ROMANS CASINO; a.k.a. KINGS ROMANS GROUP; a.k.a. ZHAO WEI NARCOTICS TRAFFICKING GROUP), Laos; Thailand; Burma; China [TCO]. Designated pursuant to section 1(a)(ii)(A) of E.O. 13581 because it is a foreign person that constitutes a significant transnational criminal organization.

2. KINGS ROMANS INTERNATIONAL (HK) CO., LIMITED (a.k.a. DOK NGEW KHAM CASINO CO. LTD.; a.k.a. DOK NGIEO KHAM COMPANY; a.k.a. DOK NGIU KHAM KING ROMAN CASINO; a.k.a. DOK NGIU KHAM KING ROMAN GROUP; a.k.a. DOKNGIEWKHAM COMPANY; a.k.a. DONG NGIEW KHAM GROUP; a.k.a. GOLDEN KAPOK; a.k.a. JIN MU MIAN; a.k.a. JING MU MIANG COMPANY; a.k.a. KING ROMANS GROUP COMPANY LTD; a.k.a. KINGS ROMAN INTERNATIONAL COMPANY, LIMITED; a.k.a. KINGS ROMAN RESORT AND CASINO; a.k.a. KINGS ROMANS CASINO; a.k.a. KINGS ROMANS GROUP; a.k.a. MYANMAR MACAU LUNDUN; a.k.a. WEI TA LEE COMPANY), Rm 3605, 36/F Wu Chung Hse, 213 Queens Rd E, Wan Chai, Hong Kong Island, Hong Kong; Registration ID 51510606 (Hong Kong); Certificate of Incorporation Number 1396649 (Hong Kong) [TCO] (Linked To: WEI, Zhao; Linked To: SU, Guiqin). Designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Zhao WEI and Guiqin SU.

3. KINGS ROMANS INTERNATIONAL INVESTMENT CO. LIMITED (a.k.a. DOK NGEW KHAM CASINO CO. LTD.; a.k.a. DOK NGIEO KHAM COMPANY; a.k.a. DOK NGIU KHAM KING ROMAN CASINO; a.k.a. DOK NGIU KHAM KING ROMAN GROUP; a.k.a. DOKNGIEWKHAM COMPANY; a.k.a. DONG NGIEW KHAM GROUP; a.k.a. GOLDEN KAPOK; a.k.a. JIN MU MIAN; a.k.a. JING MU MIANG COMPANY; a.k.a. KING ROMANS GROUP COMPANY LTD; a.k.a. KINGS ROMAN RESORT AND CASINO; a.k.a. KINGS ROMANS CASINO; a.k.a. KINGS ROMANS GROUP; a.k.a. MYANMAR MACAU LUNDUN; a.k.a. WEI TA LEE COMPANY), Rm C, 15/F, Full Win Coml Ctr, 573 Nathan Rd, Mongkok, Kowloon, Hong Kong; Rm 3605, 36FL, Wu Chung House, 213 Queen's Road East, Wan Chai, Wan Chai, Hong Kong; Registration ID 38620903 (Hong Kong); Certificate of Incorporation Number 1184117 (Hong Kong) [TCO] (Linked To: WEI, Zhao). Designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for being owned or controlled by, or having acted or purported

to act for or on behalf of, directly or indirectly, Zhao WEI.

4. KING ROMANS COMPANY LIMITED, 292, Wiang, Chiang Saen, 57150 Chiang Rai, Thailand; 292 Mu. 1, Tambon Wiang, Chiang Saen District, Chiang Rai, Thailand; 422/44 Chang Khlan Road, Tambon Chang Khlang, Mueang District, Chiang Mai, Thailand; Registration ID 0575552000132 (Thailand) [TCO] (Linked To: WEI, Zhao; Linked To: RUNGTAWANKHIRI, Nat). Designated pursuant to section 1(a)(ii)(C) of E.O. 13581 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Zhao WEI and Nat RUNGTAWANKHIRI.

Dated: January 30, 2018.

**John E. Smith,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2018-02161 Filed 2-2-18; 8:45 am]

**BILLING CODE 4810-AL-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### Notice of OFAC Sanctions Actions

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. Additionally, OFAC is publishing an update to the identifications under the Sectoral Sanctions Identification List.

**DATES:** See Supplementary Information section.

**FOR FURTHER INFORMATION CONTACT:** OFAC: Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Licensing, tel.: 202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202-622-2410.

### SUPPLEMENTARY INFORMATION:

#### Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs

are available on OFAC's website (<http://www.treasury.gov/ofac>). A complete listing of persons determined to be subject to one or more directives under Executive Order 13662 of March 20, 2014, "Blocking Property of Additional Persons Contributing to the Situation in Ukraine" (E.O. 13662), as discussed in detail in this Notice, can be found in the Sectoral Sanctions Identification List at [http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/ssi\\_list.aspx](http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/ssi_list.aspx).

### Notice of OFAC Actions

On January 26, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

#### Individuals

1. ANTIPOV, Igor Yurievich (a.k.a. ANTIPOV, Ihor), 23 Prospect Mayakovskogo, Apt. 110, Donetsk, Ukraine; 26 Ulitsa Turbinnaya, Donetsk, Ukraine; DOB 26 May 1961; Gender Male (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(v) of Executive Order 13660 of March 6, 2014, "Blocking Property of Certain Persons Contributing to the Situation in Ukraine" (E.O. 13660) for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

2. GRANOVSKY, Aleksey Ivanovich, 41 Ulitsa Malakhova, Donetsk, Donetsk Region, Ukraine; DOB 03 Nov 1973; Gender Male (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine.

Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

3. KOSTENKO, Elena Nikolaevna (a.k.a. KOSTENKO, Olena Mykolaivna), Novoannivka Street, No. 9, Krasnodonsky District, Luhansk Region, Ukraine; DOB 13 Nov 1968; POB Krasnodonsky, Ukraine; Gender Female (individual) [UKRAINE-EO13660]. Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine.

4. MALAKHOVA, Svetlana Anatolievna (a.k.a. MALAKHOVA, Svetlana Anatolyevna; a.k.a. MALAKHOVA, Svitlana Anatoliivna), 2A Levanevsky Street, Luhansk, Luhansk Region, Ukraine; DOB 27 Aug 1964; Gender Female (individual) [UKRAINE-EO13660]. Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine

without the authorization of the Government of Ukraine.

5. MALGIN, Pavel Vladimirovich (a.k.a. MALGIN, Pavlo Volodymirovich; a.k.a. MALHIN, Pavlo), Quarter Koshevogo 37, Apt. 28, Molodogvardeysk, Ukraine; Lenin Street 3, Apt. 1, Sorokino Krasnodon, Ukraine; DOB 30 Mar 1968; POB Krasnodon, Ukraine; Gender Male (individual) [UKRAINE-EO13660]. Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine.

6. MATYUSHCHENKO, Ekaterina Sergeevna (a.k.a. MATYUSHCHENKO, Ekaterina Sergeevna; a.k.a. MATYUSHCHENKO, Kateryna), 20 Ulitsa Novosadovaya, Apt. 41, Donetsk, Donetsk Region, Ukraine; DOB 01 Feb 1979; Gender Female (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine.

Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

7. MELNYCHUK, Oleksandr (a.k.a. MELNICHUK, Aleksandr Aleksandrovich), Ukraine; DOB 17 Jan 1965; POB Rovenki, Ukraine; Gender Male (individual) [UKRAINE-EO13660] (Linked To: LUHANSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, technological support for, or goods or services to or in support of, the so-called "LUHANSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

8. MELNYCHUK, Serhiy (a.k.a. MELNICHUK, Sergey; a.k.a. MELNYCHUK, Sergiy Oleksandrovich), Ukraine; DOB 30 Sep 1976; POB Rovenki, Ukraine; Gender Male (individual) [UKRAINE-EO13660] (Linked To: LUHANSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, technological support for, or goods or services to or in support of, the so-called "LUHANSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

9. NIKONOROVA, Natalya Yurievna, 7 Ulitsa Dneprodzerzhinskaya, Apt. 142, Donetsk, Donetsk Region, Ukraine; DOB 28 Sep 1984; Gender Female (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine. Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

10. OVSYANNIKOV, Dmitry Vladimirovich (Cyrillic: ОВСЯННИКОВ,

ДМИТРИЙ ВЛАДИМИРОВИЧ), Sevastopol, Crimea, Ukraine; DOB 21 Feb 1977; POB Omsk, Russia; Gender Male (individual) [UKRAINE-EO13660]. Designated pursuant to section 1(a)(i)(B) of E.O. 13660 for being responsible for or complicit in, or having engaged in, directly or indirectly, actions or policies that threaten the peace, security, stability, sovereignty, or territorial integrity of Ukraine.

11. PASHKOV, Vladimir Igorevich, Russia; Ukraine; DOB 1961; POB Bratsk, Russia; Gender Male (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "LUHANSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

12. PAVLENKO, Vladimir Nikolaevich (a.k.a. PAVLENKO, Volodymyr Mykolaiovych), Ukraine; Gender Male; Minister of State Security of the so-called Donetsk People's Republic (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

13. RADOMSKAYA, Elena Vladimirovna (a.k.a. RADOMSKA, Olena; a.k.a. RADOMSKAYA, Yelena), 211 Ulitsa Kuibysheva, Apt. 65, Donetsk, Donetsk Region, Ukraine; DOB 15 Nov 1974; Gender Female (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(ii) of E.O. 13660 for having asserted governmental authority over any part or region of Ukraine without the authorization of the Government of Ukraine.

Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

14. TIMOFEEV, Aleksandr Yurievich (a.k.a. TIMOFEYEV, Aleksandr Yuryevich; a.k.a. TYMOFEEV, Oleksandr Yuriyovich), 134 Ulitsa Petrovskogo, Apt. 98, Donetsk, Ukraine; DOB 15 May 1971; Gender Male (individual) [UKRAINE-EO13660] (Linked To: DONETSK PEOPLE'S REPUBLIC). Designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called "DONETSK PEOPLE'S REPUBLIC," a person determined to be subject to E.O. 13660.

15. CHEREZOV, Andrey Vladimirovich (a.k.a. CHEREZOV, Andrei; a.k.a. CHEREZOV, Andrey), Russia; DOB 12 Oct 1967; POB Salair, Kemerovskaya Oblast, Russia; nationality Russia; Gender Male; Deputy Minister of Energy in the Department

of Operational Control and Management in the Electric Power Industry (individual) [UKRAINE–EO13661]. Designated pursuant to section 1(a)(ii)(A) of Executive Order 13661 of March 16, 2014, “Blocking Property of Additional Persons Contributing to the Situation in Ukraine” (E.O. 13661) for being an official of the Government of the Russian Federation.

16. GRABCHAK, Evgeniy Petrovich (a.k.a. GRABCHAK, Evgeniy; a.k.a. GRABCHAK, Evgeny), Russia; DOB 18 Jul 1981; POB Ust-Labinsk, Krasnodar Region, Russia; nationality Russia; Gender Male; Head of the Department of Operational Control and Management in the Electric Power Industry in the Energy Ministry of the Russian Federation (individual) [UKRAINE–EO13661]. Designated pursuant to section 1(a)(ii)(A) of E.O. 13661 for being an official of the Government of the Russian Federation.

17. KOLOSOV, Bogdan Valeryevich (a.k.a. KOLOSOV, Bogdan), House 177, Apt. 64, Izhevsk, Udmurtskaya Respublika 426060, Russia; DOB 06 May 1985; Gender Male (individual) [UKRAINE–EO13661] (Linked To: KALASHNIKOV CONCERN). Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, KALASHNIKOV CONCERN, a person determined to be subject to E.O. 13661.

Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, KALASHNIKOV CONCERN, a person determined to be subject to E.O. 13661.

18. PENTYA, Aleksandr Yevgenyevich (a.k.a. PENTYA, Alexander), St. Petersburg, Russia; DOB 07 Sep 1985; Gender Male (individual) [UKRAINE–EO13661] (Linked To: CJSC ABR MANAGEMENT). Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for acting or purporting to act for or on behalf of, directly or indirectly, CJSC ABR MANAGEMENT, a person determined to be subject to E.O. 13661.

19. ABRAMOV, Valeri Vyacheslavovich (a.k.a. ABRAMOV, Valerii Vyacheslavovich), St. Petersburg, Russia; 133, ul. Chernyshevskogo, Vologda, Vologodskaya Obl 160019, Russia; 122 Grazhdanskiy Prospect, Suite 5, Liter A, St. Petersburg 195267, Russia; DOB 06 Jan 1963; POB Tula, Russia; Gender Male; Tax ID No. 780201346432 (Russia); General Director (individual) [UKRAINE–EO13685] (Linked To: VAD, AO). Designated pursuant to section 2(a)(iii) of Executive Order 13685 of December 19, 2014, “Blocking Property of Certain Persons and Prohibiting Certain Transactions With Respect to the Crimea Region of Ukraine” (E.O. 13685) for having acted or purported to act for or on behalf of, directly or indirectly, VAD, AO, a person determined to be subject to E.O. 13685.

20. PEREVALOV, Viktor Pavlovich, St. Petersburg, Russia; 133, ul. Chernyshevskogo, Vologda, Vologodskaya Obl 160019, Russia; 122 Grazhdanskiy Prospect, Suite 5, Liter A, St. Petersburg 195267, Russia; DOB 27 Jun 1963; Gender Male; Tax ID No. 780201527164 (Russia); First Deputy General Director (individual) [UKRAINE–EO13685]

(Linked To: VAD, AO). Designated pursuant to section 2(a)(iii) of E.O. 13685 for having acted or purported to act for or on behalf of, directly or indirectly, VAD, AO, a person determined to be subject to E.O. 13685.

21. TOPOR–GILKA, Sergey Anatolyevich, Russia; DOB 17 Feb 1970; Gender Male;

Director General of Limited Liability Company Foreign Economic Association Technopromexport (individual) [UKRAINE–EO13685] (Linked To: LIMITED LIABILITY COMPANY FOREIGN ECONOMIC ASSOCIATION TECHNOPROMEXPORT). Designated pursuant to section 2(a)(iii) of E.O. 13685 for having acted or purported to act for or on behalf of, directly or indirectly, LIMITED LIABILITY COMPANY FOREIGN ECONOMIC ASSOCIATION TECHNOPROMEXPORT, a person determined to be subject to E.O. 13685.

Also designated pursuant to section 2(a)(iii) of E.O. 13685 for having acted or purported to act for or on behalf of, directly or indirectly, OTKRYTOE AKTSIONERNOE OBSHCHESTVO VNESHNEKONOMICHESKOE OBEDINENIE TEKHNOPROMEKSPORT, a person determined to be subject to E.O. 13685.

#### Entities

1. DONCOALTRADE SP Z O O, Ul. Barbary 21, Katowice, woj. Slaskie, pow. M. Katowice 40–053, Poland; Registration ID 0000421465 (Poland) [UKRAINE–EO13660] (Linked To: MELNYCHUK, Oleksandr). Designated pursuant to section 1(a)(v) of E.O. 13660 for being owned or controlled by Oleksandr MELNYCHUK, a person determined to be subject to E.O. 13660.

2. KOMPANIYA GAZ-ALYANS, OOO (a.k.a. COMPANY GAZ-ALLIANCE LLC; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU KOMPANIYA GAZ-ALYANS), 15 Ul. Svobody, Nizhni Novgorod, Nizhegorodskaya Obl. 603003, Russia; Registration ID 1142311010885 (Russia) [UKRAINE–EO13660] (Linked To: DONETSK PEOPLE’S REPUBLIC; Linked To: LUHANSK PEOPLE’S REPUBLIC; Linked To: ZAO VNESHTORGSERVIS). Designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ZAO VNESHTORGSERVIS, a person determined to be subject to E.O. 13660.

Also designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the so-called “DONETSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

Also designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the so-called “LUHANSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

3. UGOLNYE TEKHNOLOGII, OOO (a.k.a. COAL TECHNOLOGIES; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU “UGOLNYE TEKHNOLOGII”), d. 25 ofis 13, 14, per.

Avtomobilny, Rostov-on-Don, Rostovskaya Oblast 344038, Russia; Registration ID 1146164002621 [UKRAINE–EO13660] (Linked To: DONETSK PEOPLE’S REPUBLIC; Linked To: LUHANSK PEOPLE’S REPUBLIC). Designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the so-called “DONETSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

Also designated pursuant to section 1(a)(iv) of E.O. 13660 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the so-called “LUHANSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

4. ZAO VNESHTORGSERVIS, 1 Geroyev Street, Tskhinval, South Ossetia, Georgia [UKRAINE–EO13660] (Linked To: DONETSK PEOPLE’S REPUBLIC; Linked To: LUHANSK PEOPLE’S REPUBLIC). Designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called “DONETSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

Also designated pursuant to section 1(a)(v) of E.O. 13660 for having acted or purported to act for or on behalf of, directly or indirectly, the so-called “LUHANSK PEOPLE’S REPUBLIC,” a person determined to be subject to E.O. 13660.

5. EVRO POLIS LTD. (a.k.a. EVRO POLIS, OOO; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU EVRO POLIS), d. 1A pom. 9.1A, Shosse Ilinskoe, Krasnogorsk, Krasnogorski Raion, Moskovskaya Obl. 143409, Russia; Registration ID 1165024055613 [UKRAINE–EO13661] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich). Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for being owned or controlled by Yevgeniy PRIGOZHIN, a person determined to be subject to E.O. 13661.

6. INSTAR LODZHISTIKS, OOO (a.k.a. INSTAR LOGISTICS), d. 20 str., 7 ofis 102V, ul. Elektroavodskaya, Moscow 1072023, Russia; Registration ID 1027739429981 (Russia); Tax ID No. 7714136948 (Russia); Government Gazette Number 18631592 (Russia) [UKRAINE–EO13661]. Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, KALASHNIKOV CONCERN, a person determined to be subject to E.O. 13661.

Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, KALASHNIKOV CONCERN, a person determined to be subject to E.O. 13661.

7. PJSC POWER MACHINES (a.k.a. OPEN JOINT STOCK COMPANY POWER MACHINES—ZTL, LMZ, ELECTROSILA, ENERGOEXPORT; a.k.a. PUBLICHNOE AKTSIONERNOE OBSHCHESTVO SILOVYE MASHINY—ZTL, LMZ, ELEKTROSILA, ENERGOEXPORT; a.k.a. SILOVYE

MASHINY, PAO), 3A Vatutina St., St. Petersburg 195009, Russia; Registration ID 102770004012 (Russia) [UKRAINE—EO13685]. Designated pursuant to section 2(a)(iv) of E.O. 13685 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, LIMITED LIABILITY COMPANY FOREIGN ECONOMIC ASSOCIATION TECHNOPROMEXPORT, a person determined to be subject to E.O. 13685.

Also designated pursuant to section 2(a)(iv) of E.O. 13685 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, OTKRYTOE AKTSIONERNOE OBSHCHESTVO VNESHNEEKONOMICHESKOE OBEDINENIE TEKHNOPROMEKSPORT, a person determined to be subject to E.O. 13685.

8. LIMITED LIABILITY COMPANY FOREIGN ECONOMIC ASSOCIATION TECHNOPROMEXPORT (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVESTVENNOSTYU VNESHNEEKONOMICHESKOE OBEDINENIE TEKHNOPROMEKSPORT; a.k.a. OOO VO TECHNOPROMEXPORT; a.k.a. OOO VO TPE), Novyi Arbat Str. 15, Building 2, Moscow 119019, Russia; Registration ID 1147746527279 (Russia); Tax ID No. 7704863782e (Russia) [UKRAINE—EO13685]. Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

9. VAD, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO VAD; a.k.a. AO, VAD; a.k.a. CJSC VAD; a.k.a. JOINT STOCK COMPANY VAD; a.k.a. JSC VAD; a.k.a. ZAO VAD; a.k.a. “HIGH-QUALITY HIGHWAYS”), 133, ul. Chernyshevskogo, Vologda, Vologodskaya Obl 160019, Russia; 122 Grazhdanskiy Prospekt, Suite 5, Liter A, St. Petersburg 195267, Russia; website [www.zaovad.com](http://www.zaovad.com); Email Address [office@zaovad.com](mailto:office@zaovad.com); Registration ID 1037804006811 (Russia); Tax ID No. 7802059185 (Russia); Government Gazette Number 34390716 (Russia) [UKRAINE—EO13685]. Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

On January 26, 2018, OFAC determined SURGUTNEFTEGAS owns, directly or indirectly, a 50 percent or greater interest in the entities listed below. As a result of such ownership, these entities are subject to the prohibitions of Directive 4 (as amended) of October 31, 2017, issued pursuant to E.O. 13662, 31 CFR 589.406 and 589.802, and following the Secretary of the Treasury’s determination of July 16, 2014 pursuant to section 1(a)(i) of E.O. 13662 with respect to the energy sector of the Russian Federation economy. These entities are being identified in the Sectoral Sanctions Identification List:

1. KALININGRADNEFTEPRODUKT OOO (a.k.a. KALININGRADNEFTEPRODUKT LLC; a.k.a. LIMITED LIABILITY COMPANY KALININGRADNEFTEPRODUKT; a.k.a. LLC KALININGRADNEFTEPRODUKT), 22-b

Komsomolskaya Ulitsa, Central District, Kaliningrad, Russia; Email Address [knp@baltnet.ru](mailto:knp@baltnet.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1023900589240 (Russia); Tax ID No. 3900000136 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

2. KINEF OOO (a.k.a. KINEF, LLC; a.k.a. LIMITED LIABILITY COMPANY PRODUCTION ASSOCIATION KIRISHINEFTEORGSIINTEZ; a.k.a. LLC KINEF), d. 1 Shosse Entuziastov, Kirishi, Leningradskaya Oblast 187110, Russia; website <http://www.kinef.ru>; Email Address [kinef@kinef.ru](mailto:kinef@kinef.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1024701478735 (Russia); Tax ID No. 4708007089 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

3. KIRISHIAVTOSERVIS OOO (a.k.a. LIMITED LIABILITY COMPANY KIRISHIAVTOSERVIS; a.k.a. LLC KIRISHIAVTOSERVIS), Lit A, 12 Smolenskaya Ulitsa, St. Petersburg 196084, Russia; website [www.kirishiavtoservis.ru](http://www.kirishiavtoservis.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1057807804064 (Russia); Tax ID No. 7840016802 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

4. LENGIPRONEFTEKHIM OOO (a.k.a. INSTITUT PO PROEKTIROVANIYU PREDPRIYATIY NEFTEPERERABATYVAYUSCHEY I NEFTEKHIMICHESKOY PROMYSHLENNOSTI, LIMITED LIABILITY COMPANY; a.k.a. LIMITED LIABILITY COMPANY OIL REFINING AND PETROCHEMICAL FACILITIES DESIGN INSTITUTE; a.k.a. LLC LENGIPRONEFTEKHIM), D. 94, Obvodnogo Kanala, nab, St. Petersburg 196084, Russia; Email Address [lgnc@lgnc.spb.ru](mailto:lgnc@lgnc.spb.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1057803105755 (Russia); Tax ID No. 7810327462 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

5. MEDIA-INVEST OOO (a.k.a. LIMITED LIABILITY COMPANY MEDIA-INVEST; a.k.a. LLC MEDIA-INVEST), 17, Bld 1, Zubovskiy Boulevard, Moscow 119847, Russia; Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia;

Registration ID 1077762407580 (Russia); Tax ID No. 7704667322 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

6. NOVGORODNEFTEPRODUKT OOO (a.k.a. LIMITED LIABILITY COMPANY NOVGORODNEFTEPRODUKT; a.k.a. LLC NOVGORODNEFTEPRODUKT; a.k.a. NOVGORODNEFTEPRODUKT LLC), d. 20 Germana Ulitsa, Veliky Novgorod, Novgorodskaya Oblast 173002, Russia; Email Address [office@nnp.surgutneftegas.ru](mailto:office@nnp.surgutneftegas.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1025300788644 (Russia); Tax ID No. 5321059365 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

7. PSKOVNEFTEPRODUKT OOO (a.k.a. LIMITED LIABILITY COMPANY MARKETING ASSOCIATION PSKOVNEFTEPRODUKT; a.k.a. LLC PSKOVNEFTEPRODUKT), 4 Oktyabrskiy Prospekt, Pskov 180000, Russia; website <http://www.pskovnefteprodukt.ru>; Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1026000970049 (Russia); Tax ID No. 6027042337 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

8. SNGB AO (a.k.a. CLOSED JOINT STOCK COMPANY SURGUTNEFTEGASBANK (ZAO SNGB); a.k.a. JOINT STOCK COMPANY SURGUTNEFTEGASBANK; a.k.a. JSC BANK SNGB), 19 Kukuzyevitskogo Street, Surgut 628400, Russia; website [www.sngb.ru](http://www.sngb.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1028600001792 (Russia); Tax ID No. 8602190258 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

9. SO TVERNEFTEPRODUKT OOO (a.k.a. LIMITED LIABILITY COMPANY MARKETING ASSOCIATION TVERNEFTEPRODUKT; a.k.a. LLC MA TVERNEFTEPRODUKT), 6 Novotorzhskaya Ulitsa, Tver, Russia; website [www.tvernefteprodukt.ru](http://www.tvernefteprodukt.ru); Email Address [tvp@dep.tvcom.ru](mailto:tvp@dep.tvcom.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1026900510647 (Russia); Tax ID No. 6905041501 (Russia); For more information, please reference the following link: [http://www.treasury.gov/resource-center/sanctions/OFAC-Recent-Actions.aspx](http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx) [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

10. SOVKHOZ CHERVISHEVSKI PAO (a.k.a. OJSC SOVKHOZ CHERVISHEVSKY; a.k.a. OPEN JOINT STOCK COMPANY SOVKHOZ CHERVISHEVSKY; a.k.a. SOVKHOZ CHERVISHEVSKY, JSC), d. 81 Sovetskaya Ulitsa, S. Chervichevsky, Tyumensky Rayon, Tyumenskaya Oblast 625519, Russia; Email Address *sovxoz@list.ru*; Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1027200789142 (Russia); Tax ID No. 7224019466 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

11. STRAKHOVOVE OBSHCHESTVO SURGUTNEFTEGAZ OOO (a.k.a. INSURANCE COMPANY SURGUTNEFTEGAS, LLC; a.k.a. LIMITED LIABILITY COMPANY INSURANCE COMPANY SURGUTNEFTEGAS; a.k.a. LLC INSURANCE COMPANY SURGUTNEFTEGAS), 9/1 Lermontova Ulitsa, Surgut 628418, Russia; website [www.sngi.ru](http://www.sngi.ru); Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1028600581811 (Russia); Tax ID No. 8602103061 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

12. SURGUTMEBEL OOO (a.k.a. LIMITED LIABILITY COMPANY SYRGUTMEBEL; a.k.a. LLC SURGUTMEBEL; a.k.a. LLC SYRGUTMEBEL; a.k.a. SURGUTMEBEL, LLC), Vostochnaya Industrial 1 Territory 2, Poselok Barsovo, Surgutsky District, Yugra, Khanty-Mansiysky Autonomous Okrug, Russia; website <http://surgutmebel.ru>; Email Address *realsbt@surgutneftegaz.ru*; Executive Order 13662 Directive Determination—Subject to Directive 4; Nationality of Registration Russia; Registration ID 1028601679688 (Russia); Tax ID No. 8617013396 (Russia); For more information, please reference the following link: <http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/OFAC-Recent-Actions.aspx> [UKRAINE—EO13662] (Linked To: SURGUTNEFTEGAS).

Dated: January 29, 2018.

**John E. Smith,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2018–02149 Filed 2–2–18; 8:45 am]

**BILLING CODE 4810–AL–P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0149]

### Agency Information Collection Activity Under OMB Review: Application for Conversion

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.082

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to “OMB Control No. 2900–0149” in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to “OMB Control No. 2900–0149” in any correspondence.

#### SUPPLEMENTARY INFORMATION:

**Authority:** 44 U.S.C. 3501–21.

**Title:** Application for Conversion VA Form 29–0152.

**OMB Control Number:** 2900–0149.

**Type of Review:** Reinstatement of a Previously Approved Collection.

**Abstract:** This form is used by Veterans to convert to a permanent plan of insurance. The information on the form is required by law, U.S.C. 1904 and 1942. This form was allowed to expire due to high level of work volume and staffing changes.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register**

Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 230 on December 1, 2017, page 57028.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** 1,125 Hours.

**Estimated Average Burden per Respondent:** 15 minutes.

**Frequency of Response:** Once.

**Estimated Number of Respondents:** 4,500.

By direction of the Secretary.

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018–02217 Filed 2–2–18; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0262]

### Agency Information Collection Activity Under OMB Review: Designation of Certifying Official

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to “OMB Control No. 2900–0262” in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to “OMB

Control No. 2900–0262” in any correspondence.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Public Law 96–342.

**Title:** Designation of Certifying Official (VA Form 22–8794).

**OMB Control Number:** 2900–0262.

**Type of Review:** Extension of a currently approved collection.

**Abstract:** VA Form 22–8794 provides VA with the names and signatures of those persons authorized to certify and submit to VA any new hours or changes in the enrollment of their VA students.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 57030 on December 1, 2017, page 57030.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** 448 hours.

**Estimated Average Burden per**

**Respondent:** 10 minutes.

**Frequency of Response:** Annual.

**Estimated Number of Respondents:** 2,688.

By direction of the Secretary:

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018–02219 Filed 2–2–18; 8:45 am]

**BILLING CODE 8320–01–P**

**DEPARTMENT OF VETERANS AFFAIRS**

[OMB Control No. 2900–0179]

**Agency Information Collection Activity Under OMB Review: Application for Change of Permanent Plan—Medical**

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to “OMB Control No. 2900–0179” in any correspondence.

**FOR FURTHER INFORMATION CONTACT:**

Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to “OMB Control No. 2900–0179” in any correspondence.

**SUPPLEMENTARY INFORMATION:**

**Authority:** 44 U.S.C. 3501–21.

**Title:** Application for Change of Permanent Plan—Medical VA Form 29–1549.

**OMB Control Number:** 2900–0179.

**Type of Review:** Reinstatement of a Previously Approved Collection.

**Abstract:** These forms are used by veterans to apply to change his/her plan of insurance from a higher reserve to a lower reserve. The information on the form is required by law, 38 CFR Sections 6.48 and 8.36. This form was allowed to expire due to high level of work volume and staffing changes.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 230 on December 1, 2017, page 57029.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** 14 Hours.

**Estimated Average Burden Per Respondent:** 20 minutes.

**Frequency of Response:** On occasion.

**Estimated Number of Respondents:** 28.

By direction of the Secretary:

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018–02218 Filed 2–2–18; 8:45 am]

**BILLING CODE 8320–01–P**

**DEPARTMENT OF VETERANS AFFAIRS**

[OMB Control No. 2900–0710]

**Agency Information Collection Activity: VSO Access to VHA Electronic Health Records**

**AGENCY:** Veterans Health Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** Veterans Health Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before April 6, 2018.

**ADDRESSES:** Submit written comments on the collection of information through Federal Docket Management System (FDMS) at [www.Regulations.gov](http://www.Regulations.gov) or to Brian McCarthy, Office of Regulatory and Administrative Affairs (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to [Brian.McCarthy4@va.gov](mailto:Brian.McCarthy4@va.gov). Please refer to “OMB Control No. 2900–0710” in any correspondence. During the comment period, comments may be viewed online through FDMS.

**FOR FURTHER INFORMATION CONTACT:** Brian McCarthy at (202) 615–9241.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA’s functions, including whether the information will have practical utility; (2) the accuracy of VHA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or the use of other forms of information technology.

**Authority:** 38 U.S.C. Parts 51 and 52.

**Title:** VSO Access to VHA Electronic Health Records, VA Form 10-0400.

**OMB Control Number:** 2900-0710.

**Type of Review:** Extension of a currently approved collection.

**Abstract:** The information is being used to establish VA Veterans Health Information Systems Technology Architecture (VistA) computer accounts for Veteran Service Officers (VSO's) who have been granted Power Of Attorney by veterans who have medical information recorded in VA electronic health records. This information is collected under the authority of Title 38, CFR parts 51 and 52, Veterans Benefits.

The information will be used by VHA Office of Health Information Governance and/or contractors to create accounts in the VistA computer system for VSO's. The information collected is used for a national roll-out of a project targeted at providing more efficient benefits processing services to veterans. The VistA system requires a minimal set of data to create an account, which has been reflected on the form. After the initial roll-out, the burden to the government will be minimal, only involving VSO staff turnover.

**Affected Public:** Individuals or Households.

**Estimated Total Annual Burden:** 17 hours.

**Estimated Average Burden per Respondent:** 2 minutes.

**Frequency of Response:** Yearly.

**Estimated Number of Respondents:** 500.

By direction of the Secretary.

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018-02221 Filed 2-2-18; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0005]

### Agency Information Collection Activity under OMB Review: Application For Dependency and Indemnity Compensation by Parent(s) (Including Accrued Benefits and Death Compensation when Applicable)

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-0005" in any correspondence.

#### FOR FURTHER INFORMATION CONTACT:

Cynthia Harvey-Pryor, Office of Quality, Privacy and Risk, Department of Veterans Affairs, 811 Vermont Avenue, Floor 5, Area 368, Washington, DC 20420, (202) 461-5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to "OMB Control No. 2900-0005" in any correspondence.

#### SUPPLEMENTARY INFORMATION:

**Authority:** 38 U.S.C. 1121, 1310, 5121.

**Title:** Application For Dependency and Indemnity Compensation by Parent(s) (Including Accrued Benefits and Death Compensation when Applicable)

**OMB Control Number:** 2900-0005.

**Type of Review:** Extension without change of a currently approved collection.

**Abstract:** 38 U.S.C. 1121 and 1310 provide for payment of Dependency and Indemnity Compensation (DIC) or death compensation to parents of a Veteran whose death is service-connected. Parents must also meet income limitations to be eligible for benefits. 38 U.S.C. 5121 provides for payment of accrued benefits. VBA uses 21P-535 to collect the information necessary to determine a surviving parent's eligibility to Parents' DIC benefits.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection

of information was published at XX FR XXXXX on December XX, 2017.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** 4,320.

**Estimated Average Burden per Respondent:** 72 minutes.

**Frequency of Response:** Once.

**Estimated Number of Respondents:** 3,600.

By direction of the Secretary.

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018-02215 Filed 2-2-18; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

### Publication of Choice Act Section 201 Independent Assessments and Report—Change of Website Location

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** This **Federal Register** Notice announces a change in website location of a 2015 report entitled, "Independent Assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs (Independent Assessment Report)." The Independent Assessment Report was required by Section 201 of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act). Section 201 also required the Secretary of Veterans Affairs (VA) to publish the Report in the **Federal Register** and on a Department internet website accessible to the public. VA published the **Federal Register** Notice, which included the website address on September 18, 2015.

**ADDRESSES:** The Independent Assessment Report is now available on the following website: <https://www.va.gov/HEALTHPOLICYPLANNING/section1.asp>.

#### FOR FURTHER INFORMATION CONTACT:

Laura Bowman, Program Analyst, Veterans Health Administration, 810 Vermont Avenue NW, Washington, DC 20420 Telephone: (202) 461-7100. (This is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Section 201 of the Choice Act required the Secretary to contract with a private entity to conduct an independent assessment of VA health care. Within 60 days of completing the assessment, the private entity was required to submit a report of its findings and recommendations. The Secretary was then required to publish the report in

the **Federal Register** and on a publicly accessible website of the Department. VA published the **Federal Register** Notice on September 18, 2015 (80 FR 56550). VA also published the Independent Assessment Report on its website at [https://www.va.gov/opa/choiceact/factsheets\\_and\\_details.asp](https://www.va.gov/opa/choiceact/factsheets_and_details.asp). Since then, VA has simplified the website content to give Veterans easier access to practical information about eligibility and participation in the Veterans' Choice Program. As part of this redesign, VA moved the Independent Assessment Report to <https://www.va.gov/HEALTHPOLICY/PLANNING/section1.asp>. This **Federal Register** Notice informs the public of this change so that Veterans and other stakeholders will continue to have access to these important resources.

#### Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the **Federal Register** for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrissee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on January 23, 2018, for publication.

Approved: January 23, 2018.

#### Jeffrey Martin,

*Impact Analyst, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

[FR Doc. 2018-02158 Filed 2-2-18; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0463]

### Agency Information Collection Activity Under OMB Review: Notice of Waiver of Compensation or Pension To Receive Military Pay and Allowances

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected

cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-0463" in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 811 Vermont Avenue NW, Washington, DC 20420, (202) 461-5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to "OMB Control No. 2900-0463" in any correspondence.

#### SUPPLEMENTARY INFORMATION:

**Authority:** 44 U.S.C. 3501-21.

**Title:** Notice of Waiver of VA Compensation or Pension to Receive Military Pay and Allowances (VA Forms 21-8951 and 21-8951-2).

**OMB Control Number:** 2900-0463.

**Type of Review:** Re-instatement of a currently approved collection.

**Abstract:** VA Forms 21-8951 and 21-8951-2 are used by reservists/guardsmen to file a waiver a VA disability benefits in order to receive active or inactive duty training pay.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 213 on November 06, 2017, page 51482.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** 3,500 hours.

**Estimated Average Burden per Respondent:** 10 minutes.

**Frequency of Response:** One time.

**Estimated Number of Respondents:** 21,000.

By direction of the Secretary.

#### Cynthia Harvey-Pryor,

*Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018-02220 Filed 2-2-18; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0024]

### Agency Information Collection Activity Under OMB Review: Insurance Deduction Authorization

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before March 7, 2018.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-0024" in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461-5870 or email [cynthia.harvey-pryor@va.gov](mailto:cynthia.harvey-pryor@va.gov). Please refer to "OMB Control No. 2900-0024" in any correspondence.

#### SUPPLEMENTARY INFORMATION:

**Authority:** 44 U.S.C. 3501-21.

**Title:** Insurance Deduction Authorization VA Form 29-888.

**OMB Control Number:** 2900-0024.

**Type of Review:** Reinstatement of a Previously Approved Collection.

**Abstract:** These forms are used by veterans to authorize the Department of Veterans Affairs (VA) to make deductions from benefit payments to pay premiums, loans and/or liens on his/her insurance contract. The information requested is authorized by law, 38 CFR 8.8. This form was allowed to expire due to high level of work volume and staffing changes.

An agency may not conduct or sponsor, and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 230 on December 1, 2017, page 57031.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 622 hours.

*Estimated Average Burden per*

*Respondent:* 10 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 3732.

By direction of the Secretary.

**Cynthia Harvey-Pryor,**

*Department Clearance Officer, Office of Office of Quality, Privacy and Risk, Department of Veterans Affairs.*

[FR Doc. 2018-02216 Filed 2-2-18; 8:45 am]

**BILLING CODE 8320-01-P**

## **DEPARTMENT OF VETERANS AFFAIRS**

### **Veterans' Family, Caregiver, and Survivor Advisory Committee; Notice of Meeting**

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Veterans' Family, Caregiver, and

Survivor Advisory Committee will meet on March 1-2, 2018. On March 1, the Committee will meet in open session at 11301 Wilshire Boulevard, Building 500, Room 1281, Los Angeles, CA, from 9:00 a.m. to 5:00 p.m. On March 2, the Committee will be touring the VA facility and breaking into small groups to participate in discussions and listening sessions with facility staff, families, caregivers, and survivors. Tours of VA facilities are closed, to protect from disclosure Veterans' information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Therefore, on March 2, the meeting will be closed to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on matters related to: Veterans' families, caregivers, and survivors across all generations, relationships, and Veterans status; the use of VA care and benefits services by Veterans' families, caregivers, and survivors, and possible expansion of such care and benefits services; Veterans' family, caregiver, and survivor experiences; VA policies, regulations, and administrative requirements related to the transition of Servicemembers from the Department of Defense (DoD) to enrollment in VA that impact Veterans' families, caregivers,

and survivors; and factors that influence access to, quality of, and accountability for services and benefits for Veterans' families, caregivers, and survivors.

On March 1, the agenda will include information briefings on VA's Veterans Experience Office, Caregiver Support Office, VA's Choose Home Initiative, and community partners. The Committee's subcommittees on Education and Awareness, Access and Eligibility, and Gaps and Innovation will report out on activities since the last meeting. Public comments will be received at 4:15 p.m. on March 1, 2018.

Individuals wishing to make a public comment should contact Lauren Barone at [laureen.barone@va.gov](mailto:laureen.barone@va.gov) and are requested to submit a 1-2 page summary of their comments for inclusion in the official meeting record. In the interest of time, each speaker will be held to a 5 minute time limit.

Any member of the public seeking additional information should contact Ms. Barone at (716) 364-3639 or at [laureen.barone@va.gov](mailto:laureen.barone@va.gov).

Dated: January 31, 2018.

**Jelessa M. Burney,**

*Federal Advisory Committee Management Officer.*

[FR Doc. 2018-02186 Filed 2-2-18; 8:45 am]

**BILLING CODE P**



# FEDERAL REGISTER

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Part II

## The President

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Proclamation 9695—American Heart Month, 2018

Proclamation 9696—National African American History Month, 2018



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# Presidential Documents

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Title 3—

Proclamation 9695 of January 31, 2018

The President

American Heart Month, 2018

By the President of the United States of America

## A Proclamation

More than 600,000 Americans die of heart disease each year, making it the leading cause of death for both men and women in the United States. In addition to remembering our lost loved ones, American Heart Month is a time to raise awareness about the risk factors, warning signs, and symptoms associated with this killer disease. This February, we renew our commitment to the battle against cardiovascular disease. With the help of our Nation's leading medical professionals and appropriate preventative measures, we hope for a future where heart disease no longer claims the lives of so many American men and women.

Thanks to ongoing advancements, medical procedures to treat heart conditions are now more precise and less invasive, recoveries are faster, and complications are fewer. We also now better understand conditions that increase the risk of heart disease among older adults—such as high blood pressure, high cholesterol, and type 2 diabetes—and more effective therapies and medications to prevent and treat them. And, we are better able to identify warning signs at an early stage.

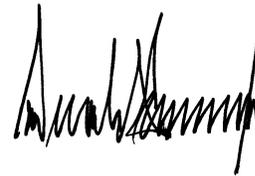
Even with these encouraging developments, nearly half of all Americans between ages 45 and 65 have heart disease or a related condition. The risk of heart disease increases with age, so for most people, prevention is the best deterrent. People should also understand that they may be subject to unique risk factors, often based on family history, which may require them to take appropriate, targeted preventative measures. Whatever risk factors they may face, there are many steps people can take to make coronary disease less likely. The most effective are eating a healthy diet, staying physically active, maintaining a healthy body weight, controlling blood pressure and cholesterol, and not smoking.

During our observance of American Heart Month, we remember those we have lost to heart attacks and other cardiovascular diseases. We honor healthcare providers and medical researchers who strive to advance both the treatment and prevention of this epidemic. And we encourage all Americans to commit to taking charge of their heart health, this month and every month.

In acknowledgement of the importance of the ongoing fight against cardiovascular disease, the Congress, by Joint Resolution approved on December 30, 1963, as amended (36 U.S.C. 101), has requested that the President issue an annual proclamation designating February as American Heart Month.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim February 2018 as American Heart Month. The First Lady and I encourage all Americans to participate in National Wear Red Day on February 2, 2018, to raise awareness and reaffirm our commitment to fighting heart disease. I also invite the Governors of the States, the Commonwealth of Puerto Rico, officials of other areas subject to the jurisdiction of the United States, and the American people to join me in recognizing and reaffirming our commitment to fighting cardiovascular disease.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of January, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.

A handwritten signature in black ink, appearing to be "Donald Trump", located on the right side of the page.

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## Presidential Documents

**Proclamation 9696 of January 31, 2018**

### **National African American History Month, 2018**

**By the President of the United States of America**

#### **A Proclamation**

This February, we celebrate National African American History Month to honor the significant contributions African Americans have made to our great Nation—contributions that stand as a testament to their resolve, resilience, and courage. Over the course of our Nation’s history, African Americans have endured egregious discrimination and bigotry. They have, nevertheless, always been determined to contribute their earnest efforts to America’s greatness.

This annual observance is an opportunity to remember the challenges of our past, but also to honor countless African-American heroes who inspire us to shape our country’s future. This year’s theme, “African Americans in Times of War,” calls our attention to the heroic contributions of African Americans during our Nation’s military conflicts, from the Revolutionary War to present-day operations.

Throughout our history, members of the Armed Forces have fought to secure freedom and liberty for all, defending our country both on our shores and in foreign lands. African Americans have shouldered an enormous share of the burden of battle in every American military engagement, donning our Nation’s military uniforms to answer the call of duty. For far too long, African Americans bravely fought and died in the name of freedom, while at the same time struggling to attain equality, respect, and the full privileges of citizenship. Because of their love of country, these heroes insisted on serving and defending America despite racial prejudice, unequal treatment, diminished opportunities, and segregation. Their valorous acts in the face of grave injustice revealed the true meaning of American patriotism—service before self.

It was not until 1948 that President Harry S. Truman ordered desegregation of the military, providing “equality of treatment and opportunity for all persons in the Armed Forces without regard to race, color, religion or national origin.” It took another 5 years before the Secretary of Defense abolished the last segregated African-American military unit. These hard won victories for justice catalyzed other victories, as they cast a harsh light on aspects of our social and civic lives that remained segregated. Those who fought against and ended segregation in the military reminded the Nation of its obligation to the self-evident truth of equality written into the Declaration of Independence.

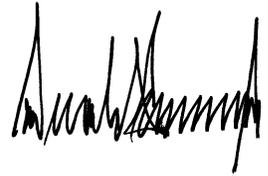
We remember soldiers like Sergeant Henry Johnson of the Harlem Hellfighters, the all-black National Guard unit that was among the first American forces to arrive in France during World War I. Johnson suffered 21 wounds during front-line combat and received France’s highest award for valor. To acknowledge his exceeding bravery, he was posthumously awarded the Distinguished Service Cross and a Purple Heart. We remember pilot Benjamin O. Davis, Jr., who commanded the famed Tuskegee Airmen and became the first African American General in the United States Air Force. We remember soldiers like Major Charity Adams Earley, who was commander of the only all-African American Women’s Army Corps unit that served overseas during World War II. She was a trailblazer in her

efforts to recruit more women to military service in spite of rampant racism and segregation.

These and countless other African Americans triumphed over ignorance, oppression, and injustice to make indelible contributions, not only to our military history, but even more importantly to our American history. They are an integral part of our Nation's story. We are indebted to the individual and collective perseverance and patriotism of these outstanding men and women, as we are to all African Americans who have served, and continue to serve in the Armed Forces of this great Nation.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim February 2018 as National African American History Month. I call upon public officials, educators, librarians, and all the people of the United States to observe this month with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of January, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.



# Reader Aids

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Alex Diekmann Peak  
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